

**REGULATORY LEGEND**

	<b>Actual Size</b>
DRUG FACTS TITLE	N/A
DRUG FACTS CONTINUED	N/A
HEADINGS	N/A
SUBHEADINGS/BODY TEXT	6 pt
LEADING	6 pt
# OF CHARACTERS PER INCH	N/A
BULLETS	N/A
SPACE BEFORE BULLET	N/A
BARLINES, HAIRLINES	N/A
SPACE BETWEEN HAIRLINES AND BOX END	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Vertical	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Horizontal	N/A

Do not use more than one lozenge at a time, or many lozenges one after another since this can cause hiccups, heartburn, nausea or other side effects.

Read all the following instructions before using **Nicorette Lozenges**. Refer to them often to make sure you're using **Nicorette Lozenges** correctly.

**IMPORTANT! Don't stop or give up if you do not like the taste of the lozenge at first. Nicorette Lozenges are a medication, not a candy. Most people get used to the taste after a day or two. Remember, sticking with the plan will help you quit.**

**Begin using Nicorette Lozenges on your quit date.**

1) Remove one **Nicorette Lozenge** from the immediate-release container. Place the lozenge in your mouth and allow the lozenge to slowly dissolve. Inhale deeply through the nose. Do not chew or swallow the lozenge. You may feel a warm or tingling sensation.

2) Occasionally move the lozenge from one side of your mouth to the other side until completely dissolved.

To reduce cravings or urges to smoke and other withdrawal symptoms, use **Nicorette Lozenges** according to the following dosage schedule:

Weeks 1 through 6	Weeks 7 through 9	Weeks 10 through 12
1 lozenge every 1 to 2 hours	1 lozenge every 2 to 4 hours	1 lozenge every 4 to 8 hours

Do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day. At the end of the 12 weeks of treatment, you will have completed treatment.

**FOR THE BEST CHANCE OF QUITTING**, use **Nicorette Lozenges** on a regular schedule, using at least 9 lozenges a day during the first 6 weeks. That will help your body better adjust to the lack of cigarettes and better help prevent cravings. Some people may need more lozenges to reduce their cravings. Do not exceed the recommended maximum daily dosage of 20 lozenges per day. Do not continuously use one lozenge after another, since this may cause hiccups, heartburn, nausea or other side effects. Do not eat or drink 15 minutes before using or while the lozenge is in your mouth.

**WALLET CARD**

**WHERE TO CALL FOR HELP**

American Lung Association  
 1-800-558-8646  
 1-800-233-2343  
 1-800-233-2344  
 American Cancer Society  
 1-800-4-A-CANCER  
 1-800-422-6237  
 1-800-422-6238  
 Quitting Now? Call 1-877-4QUIT

**CUTTING BACK ON YOUR Nicorette LOZENGE USAGE.**

The advice given for using **Nicorette Lozenges** is to decrease and gradually eliminate your need for nicotine, while you control cravings. So, as the schedule to the left indicates, you should gradually reduce the amount of **Nicorette Lozenges** you take per day. Some people find it easier to succeed by substituting ordinary candies or sugar-free candies for some of the **Nicorette Lozenges** they would normally use. As time goes on, you can increase the number of pieces of candy as you further reduce your use of **Nicorette Lozenges**. It is important to complete treatment. If you still feel the need to use **Nicorette Lozenges** to keep from smoking, after week 12, talk with your health care provider.

**MAKE QUITTING EASIER ON YOURSELF.**

Some other good ideas, parties, celebrations, and socializing may help tempt you to smoke. Please remember these tips to help you resist those urges and stay smoke-free.

**The Day You Quit Smoking**

Look to your family and friends for support. Let them know what to do to avoid doing to help you quit.

Throw away ALL cigarettes, ashtrays, matches, lighters. You don't need them. You don't want them and you want to make it difficult to go back.

Keep yourself occupied. Take a walk. See a movie. See friends. Do anything to keep your mind off cigarettes.

Calculate all the money you'll save by not buying cigarettes. Hold it over \$1,000 a year! (2000 a pack!) Think of what you can spend it on!

Know what situations are going to make you want to smoke. Plan how you will avoid them and deal with them so you don't smoke.

Make an appointment to see your dentist and get the tobacco spots cleaned off. While you're getting all of the wisdom of cigarettes in the house, do the same for your teeth. Have clothes or drapes that smell of smoking cleaned.

Have that your house cleaned. Try to spend most of your time in the house.

If you usually smoked with coffee or alcohol, try to keep away from them for now. Remember you are also trying to break a habit. Smoking is a "hand" on a habit. So use something else to occupy your hands: a coffee bar or a pen.

Have a good time to get active. Find activities to take your mind off cigarettes and relax. Take up jogging, swimming, or walking.

Don't stress out about gaining weight. Dieting may help weaken habits that put smoking. Eat healthy and exercise daily. Drink large quantities of water and fruit juices. This can help your chances of staying smoke-free.

"Lung" health advice: That's a great book. "Truth" by...

**REMEMBER** Urges to smoke are temporary. They'll pass, even if you don't smoke.

**WHAT YOU CAN EXPECT.**

As you are successful at staying smoke-free, initially you will probably notice a few of the following typical withdrawal symptoms, so don't be surprised. Use of **Nicorette Lozenges** reduces these symptoms, but may not eliminate them entirely. They will go away with time. Stay focused on your goal of becoming an ex-smoker. Research shows that if you manage to avoid all smoking in the first week that means not having a single puff, your chance of success dramatically increases.

**The First Few Days.** You may feel nervous or irritable or have difficulty concentrating during the first few days after you quit smoking. Your body needs time to begin balance. Initially, you might feel a little out of sorts, get headaches, feel light-headed, or have trouble sleeping. Your stomach might get upset before it improves. If it's a positive sign. Coughing helps clean your lungs of the tar residue you quit from smoking.

**After a Couple of Weeks.** Your confidence and ability to cope with urges to smoke should be getting stronger. But don't be over-confident. You can smoke just one cigarette. Even then, having even a single puff can lead to relapse to smoking. Cigarettes regularly be prepared, and remember why you wanted to stop smoking. Have you noticed that your sense of taste and smell has improved? You are probably coughing less and finding it easier to breathe. You've also probably noticed your withdrawal symptoms are subsiding through don't worry if they're still there. There are all positive signs that your body is getting used to your successful stopping of smoking.

**By The End of the First Month.** You are less likely to have cravings for cigarettes as often. However, sudden cravings may still happen, and when they do, be on your guard. They can be strong and seem to come out of the blue. Be prepared for these challenging times. The key is to do what you can to ease unexpected cravings and keep yourself on the way you now smoke. Be more observant than smokers. That means snacks before. These bodies and hair are better. That skin can be clearer and brighter. Their skin is less likely to wrinkle. Not smoking around children and pets is healthier for them.

**WHAT IF YOU DO SLIP AND SMOKE?**

"What if I relapse?" One cigarette is a slip-up, but it's not the end of the quit effort. Everybody slips at something. The key is this:

forget yourself and stop at that one cigarette. Don't let this slip ruin your good intentions, keep at your quit attempt. So, throw out your cigarettes and continue with your quit attempt, keeping in mind what went wrong and how to fix it.

If you do go back to smoking, certainly don't throw out your **Nicorette Lozenges**. Keep them for the next time you're ready to quit. In fact, research says that even if you are back to smoking regularly the best thing you can do is learn and try again.

Try to understand the reason you had those cigarettes that made you slip. That's important, because now you can plan better to deal with these moments next time. It's true you stumbled. So don't think of yourself as having failed. Encourage yourself for trying the best attempt at a learning experience, even a "trial run" for the real thing.

Take a look at the usage instructions and check that you used the **Nicorette Lozenges** correctly and for the full 12 weeks of the program. When you try again make sure you use enough and the right way. That way you'll be best equipped to deal with the unexpected cravings.

Don't forget, calling 1-877-4QUIT and 1-800-233-2343 or 1-800-422-6237, 1-800-422-6238.

**YOU'VE MADE IT!**

Once your twelve week quitting program is over, you've taken your last **Nicorette Lozenge**. Now you are both cigarette and nicotine free. Get up and give yourself a standing ovation. We mean it. Do you realize that you have just done a really difficult thing?

Now it's a good time to think back on the process. Think of all your reasons for quitting smoking. Think of your goals. Think of how things are going to be a reality now.

Think of what you're going to do with your newly liberated cigarette money. The places you can now go smoke free. Think of the nice time you may have added to your life and what you can do with it. And although you may still experience the occasional temptation, and cigarettes still want you back, think positively. Think forward. And consider yourself a proud non-smoker.

**FREQUENTLY ASKED QUESTIONS:**

**1. What's the best smoking and least using Nicorette Lozenges how will I feel?**

**Nicorette Lozenges** help reduce cravings, but be prepared for some nicotine withdrawal symptoms. After you stop smoking they can begin almost at once and normally last about three or four days. For some people, any of the following may occur:

- increased craving for cigarettes
- anxiety, irritability, restlessness, mood changes, nervousness
- trouble concentrating
- increased appetite and weight gain
- headaches, muscular pain, constipation, fatigue

**Nicorette Lozenges** are designed to reduce the craving for nicotine you used to satisfy with cigarettes. **Nicorette Lozenges** also help reduce relief from other withdrawal symptoms such as irritability and nervousness.

**2. Are Nicorette Lozenges just satisfying one type of nicotine addiction for another?**

**Nicorette Lozenges** do contain nicotine. However, there is probably less nicotine in your daily dose of lozenges than in your cigarettes. **Nicorette Lozenges** give you enough nicotine to help combat the physical withdrawal symptoms, so you can cope with the mental side of stopping smoking. Also, since the nicotine from the lozenges goes into your blood stream more slowly, it reduces some of the effects of nicotine that people find troubling (such as dizziness or drowsiness) during the 12-week program. **Nicorette Lozenges** gradually wean you off your dependence for both nicotine and cigarettes.

**3. Can Nicorette Lozenges do any harm?**

Some people with conditions like heart disease or people taking prescription medicine for asthma or depression should not use this product without talking to their doctor. **IMPORTANT!** **Nicorette Lozenges** do contain the tar, carbon monoxide, and other toxins present in cigarette smoke.

**4. Will I put on weight?**

In the first couple of months after quitting smoking, some people do put on a few pounds. But think of it this way. Overall, you'll be healthier and look better. You can always back your weight by changing your diet and increasing the amount you exercise once you have gotten through the difficult part of stopping smoking.

**5. Does taking Nicorette Lozenges cost more than smoking?**

If you normally smoke a pack and a half a day, your total cost of using **Nicorette Lozenges** during the 12-week period is about the same as smoking. But guess what? After you've finished the **Nicorette Lozenge** program all that money you used to spend on cigarettes is now savings. And that's one of the health issues you'll hopefully be able to avoid.

**6. What if I have a cigarette and start smoking?**

Don't panic. First, don't think badly of yourself. Throw away your cigarettes and forgive yourself. Then think about what went wrong and get back on track. In fact, people who have already tried to stop smoking are more likely to be successful the next time.

**CHALLENGES TO WATCH FOR.**

Once you quit smoking, you are likely to experience periodic, and sometimes intense, temptations to smoke. Certain situations present special challenges. Some common ones include:

- Stress and upset
- When you are feeling stressed or upset, you may think a cigarette will make everything better. It won't. Find other ways to relax and unwind.
- The blues
- You may be especially vulnerable when you feel bored or blue. Remember that having a cigarette will just make you feel worse. Smoking uses.
- Seeing cigarettes or watching other people smoke can trigger temptation. Remember that you choose not to smoke anymore.
- Drinking and smoking seem to go together, and alcoholic beverages may weaken your resolve, making drinking dangerous to your quit effort. Avoid drinking early in your quit effort, and try to drink with non-smokers.
- Anonymity. Sometimes you may find yourself preparing to smoke without even realizing it. Watch out for those moments when your hand seems to "automatically" reach for a cigarette.

Watch out for these situations; they can trigger a relapse. You probably know which ones are most dangerous. So you plan ahead to deal with the situation effectively. Always remember that you're trying to break a habit, and the most important thing is to do something to combat the urge in these situations.

**COPIING AFTER QUITTING.**

The key to staying smoke-free is to prepare for and cope with challenges as they occur. If you find yourself tempted to smoke, do something there are some things to consider:

- Escape. Leave the situation, even for a few minutes. Most temptations don't last long.
- Distract yourself. Get your mind off smoking. Think of something else or do something else.
- Relax. Don't let stress get to you. Think of pleasant, relaxing things: breathe slowly and regularly, get the stress out of you.
- Talk yourself off of it. What you say to yourself matters. So remind yourself you can't have just one or just command yourself to STOP.

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**For more information please visit [www.nicorette.com](http://www.nicorette.com)**

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**PLACE THESE REMINDERS ON YOUR CALENDAR:**

At 8:00 AM or earlier if you quit today

**STEP 1**  
1 lozenge every 1 to 2 hours

**STEP 2**  
1 lozenge every 2 to 4 hours

**STEP 3**  
1 lozenge every 4 to 8 hours

At 8:00 AM or earlier if you quit today

**NO NEED AT THE QUIT DATE**

**How to Use Nicorette Lozenges and Tips to Help You Quit Smoking.**

**NICORETTE**  
nicotine polacrilex lozenge  
2 mg and 4 mg User's Guide  
Lozenge

**PLANNING YOUR SUCCESS**

- 1) The key to accomplishing anything important is commitment. When it comes to quitting smoking, that is especially true. **Nicorette Lozenges** can help if you really want to quit. **Nicorette Lozenges** helps with withdrawal symptoms including nicotine craving associated with quitting smoking.
- 2) Your chances of staying off cigarettes are much better if you start with at least 9 **Nicorette Lozenges** daily. For best results, use the lozenges on a regular schedule as outlined in this User's Guide.
- 3) Start using **Nicorette Lozenges** on your quit date.
- 4) This User's Guide outlines a 12-week plan for **Nicorette Lozenges**. Even though you may feel confident about your non-smoking status after a few weeks, it's important to stick with the plan to help you remain smoke-free. Even a single cigarette can put you right back to square one.
- 5) **Nicorette Lozenges** work best when used together with a support plan. See information to the right for the MyQuit behavioral support program.
- 6) After the first six weeks, start using fewer **Nicorette Lozenges**, as directed in the instructions, gradually reducing your use over the next six weeks. If you feel the need to use the lozenges for a longer period to keep from smoking, talk to your health-care provider.
- 7) If you have questions about using **Nicorette Lozenges**, call toll-free 1-800-558-8646, or talk to your pharmacist or family doctor.

**YES! YOU WANT TO QUIT!**

Wonderful. You've made the most important decision of all, to stop smoking. And by choosing **Nicorette Lozenges** to help you, you're starting on the right path. Now remember, using **Nicorette Lozenge** doesn't just mean taking a **Nicorette Lozenge**. It means setting and following a program like the one we support in this User's Guide.

Your own success depends on your effort, your level of addiction to tobacco, and your commitment to following your program.

**LET'S FACE IT.**

Quitting smoking isn't easy! You or someone you know may have tried unsuccessfully. That's why it's hard to stop smoking the first time you try. The important part is to learn from your previous attempts, understand your strengths and keep trying to quit until you succeed. Look to this User's Guide for support as you change this habit. See the guide for important information on how to use **Nicorette Lozenges** and also gives you tips to help your stop smoking. Refer back to them for advice, encouragement, and help you can count on.

**GET MOTIVATED. STAY MOTIVATED.**

Everyone has a reason for quitting — whether you're concerned about your health, your appearance, family or peer pressure, or the effect of secondhand smoke on your loved ones — all of the above, or something else entirely. Whatever your reasons, write them down. There's a wallet card on the bottom right of this User's Guide. Write your reasons on the card and carry it with you. When you have an urge to smoke or experience a difficult moment, it can help you focus on your reasons for quitting. Lots of people quit with a co-smoker, spouse or friend and use them as a quitting buddy. You can help each other out by providing extra encouragement in tough moments.

There may be support groups in your area for people trying to quit. Call your local chapter of the American Lung Association, American Cancer Society or American Heart Association for further information. Toll-free phone numbers are printed on the back of the wallet card on the bottom right of the User's Guide.

**UNDERSTANDING THE DOUBLE-EDGED SWORD.**

Smoking has two addictive components, a physical and a mental need for the nicotine in tobacco. You need to conquer both to overcome the mental side of your cigarette dependence. So once you're ready, it's time to begin. But first, read and consider the following important warnings:

**IMPORTANT WARNINGS**

This product is only for those who want to stop smoking. **If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider.** Smoking can seriously harm your unborn child.

**Ask a doctor before use if you have:**

- high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- history of seizures.

**Ask a doctor or pharmacist before use if you are:**

- using a non-nicotine stop smoking drug.
- taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.
- persistent indigestion or severe acid reflux.
- pregnant or believe you are pregnant.
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat.

**Keep out of reach of children and pets.** Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove this package, wrap it in paper and throw away the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

**YOU'RE READY TO START!**

Okay, you're ready. To become a non-smoker, start today. Now before you do anything else, you have a shot at planning to do. Read the User's Guide all the way through. You want to make sure you bought the right dose to start. If you typically smoke your first cigarette within 30 minutes of waking up, use the 2 mg **Nicorette Lozenge**. If you smoke your first cigarette more than 30 minutes after waking up, use the 4 mg **Nicorette Lozenge**. Next, plan your quitting schedule. Get a calendar to follow your progress and mark the following two important dates: the date you stop smoking and the date you stop using the lozenges.

**THE PROGRAM**

**STEP 1** Weeks 1-6: Starting on your quit date it's best to use at least 9 **Nicorette Lozenges** each day, one every 1-2 hours. This shows the day you're ready to quit is today. Place the lozenge in your mouth and allow it to slowly dissolve. Use **Nicorette Lozenges** to calm your cravings for nicotine and help you stay smoke-free. Prior to the quit date, get rid of all your cigarettes to remove temptations and make it more difficult to start smoking again.

Use a **Nicorette Lozenge** every 1 to 2 hours and at least 9 lozenges each day for the first 6 weeks to help prevent unexpected cravings and improve your chances of quitting. **These aren't ordinary lozenges.** Place the lozenge in your mouth and allow the lozenge to slowly dissolve. Do not chew or swallow the lozenge. You may feel a warm or tingling sensation. Occasionally move the lozenge from one side of your mouth to the other side until completely dissolved. **Remember to read the "USING NICORETTE LOZENGES PROPERLY" section before you take your first Nicorette Lozenge.**

**STEP 2** The next three weeks, that's weeks 7-9.

**At the beginning of week 7, start using fewer Nicorette Lozenges, one every 2-4 hours.** After six weeks, you should wait a little longer between lozenges, and lozenge every two to four hours. This will help you gradually use fewer **Nicorette Lozenges** as time goes on. Remember to read the "USING NICORETTE LOZENGES PROPERLY" section before you take your first Nicorette Lozenge.

**STEP 3** The final three weeks, that's weeks 10-12.

**At the beginning of week 10, reduce Nicorette Lozenge use even further, one every 4-8 hours.** At the beginning of week 10 further reduce the number of **Nicorette Lozenges** you use each day to reduce the amount of nicotine you get. This should do the trick by using one lozenge every 4 to 8 hours. Put the Step 3 reminder on the first day of week 10 so you know when you should be starting this last step to becoming smoke and nicotine free.

**END!** At the end of week 12 you'll complete **Nicorette Lozenge** therapy. For the 12-week period, remember on your calendar or on the date 12 weeks after the day you stopped smoking and started using **Nicorette Lozenges**.

Since smoking is an addiction, it's hard to quit. Even after you quit, there will be times when you WANT a cigarette, sometimes strongly. Use this section on **"CHALLENGES TO WATCH FOR!"** The best defense is to be prepared. Plan now for handling tough times as you go on. Think about situations where you usually get an urge to smoke or where you might experience strong urges to smoke (for example, spending time with smokers or drinking alcohol) — try to avoid these situations if those things tempt you to smoke.

Change your habits. Take your coffee break somewhere else. Take a walk. Break the association between your usual habit and cigarettes.

If you do encounter a situation where you feel a strong urge to smoke, fight it! Take a break from the situation, keep yourself busy or distract with other activities, remind yourself why you want to quit, and that having "just one" will really hurt your goal of quitting!

Assemble a "survival package" — items that can keep you distracted in case you get an urge to smoke. For example, cinnamon gum or hard candy, relaxing music, things to keep your hands busy like a smooth stone or paper clips, etc.

Track your quit progress. Use a journal or the MyQuit app on your mobile phone to note and when you get an urge to smoke. Note how many pieces of **Nicorette Lozenges** you use each day, if you slip and have a cigarette, don't give up. Stop smoking again and get back on your program with **Nicorette Lozenges**.

Establish your support network. Keep friends and family members' phone numbers ready to get the moral support you need. Before quitting, ask friends and family to support and encourage you. Think of specific ways they can help.

Reward yourself! Set aside little gifts to encourage yourself which you can earn by overcoming difficult hurdles.

**HOW NICORETTE LOZENGES WORK**

**Nicorette Lozenges** are a form of Nicotine Replacement Therapy. They deliver nicotine to your body, temporarily relieving nicotine and nicotine withdrawal symptoms when you quit smoking, but unlike cigarettes, **Nicorette Lozenges** deliver a lower, steady level of nicotine to your blood. When used as directed, **Nicorette Lozenges** help you regulate nicotine and gradually reduce your body's craving for nicotine.

The good news is that **Nicorette Lozenges** contain no tar or carbon monoxide, and therefore don't present the same medical risks as cigarettes.

However, the lozenges still deliver nicotine, the addictive ingredient in cigarettes. And for some people the nicotine in **Nicorette Lozenges** can occasionally cause mouth or throat irritation, headache, nausea, dizziness, upset stomach, etc. —

**USING NICORETTE LOZENGES PROPERLY:**

Remember, **Nicorette Lozenges** aren't the ordinary lozenges such as cough drops. This lozenge is designed to deliver nicotine into your system through the lining of your mouth, not in your stomach like most other medications. It is important to minimize swallowing the dissolved medicine in the lozenge so that it can be properly absorbed in your mouth.

**MyQuit**

Program brought to you by

**NICORETTE**  
nicotine polacrilex lozenge  
Lozenge  
and Halcion

**NICORETTE** has created the **MyQuit** program to provide you with support whenever and wherever you need it. The program provides a network of tools to help you get through those tough moments.

To Your Inbox: Stay motivated with our personalized email support program that sends encouragement and tips straight to your inbox.

On The Web: Get helpful advice, tips and inspiration from smokers.org on www.Nicorette.com.

On The Go: Log cravings and track your personal quit time on your mobile phone with the MyQuit App.

To learn more visit [www.Nicorette.com](http://www.Nicorette.com)

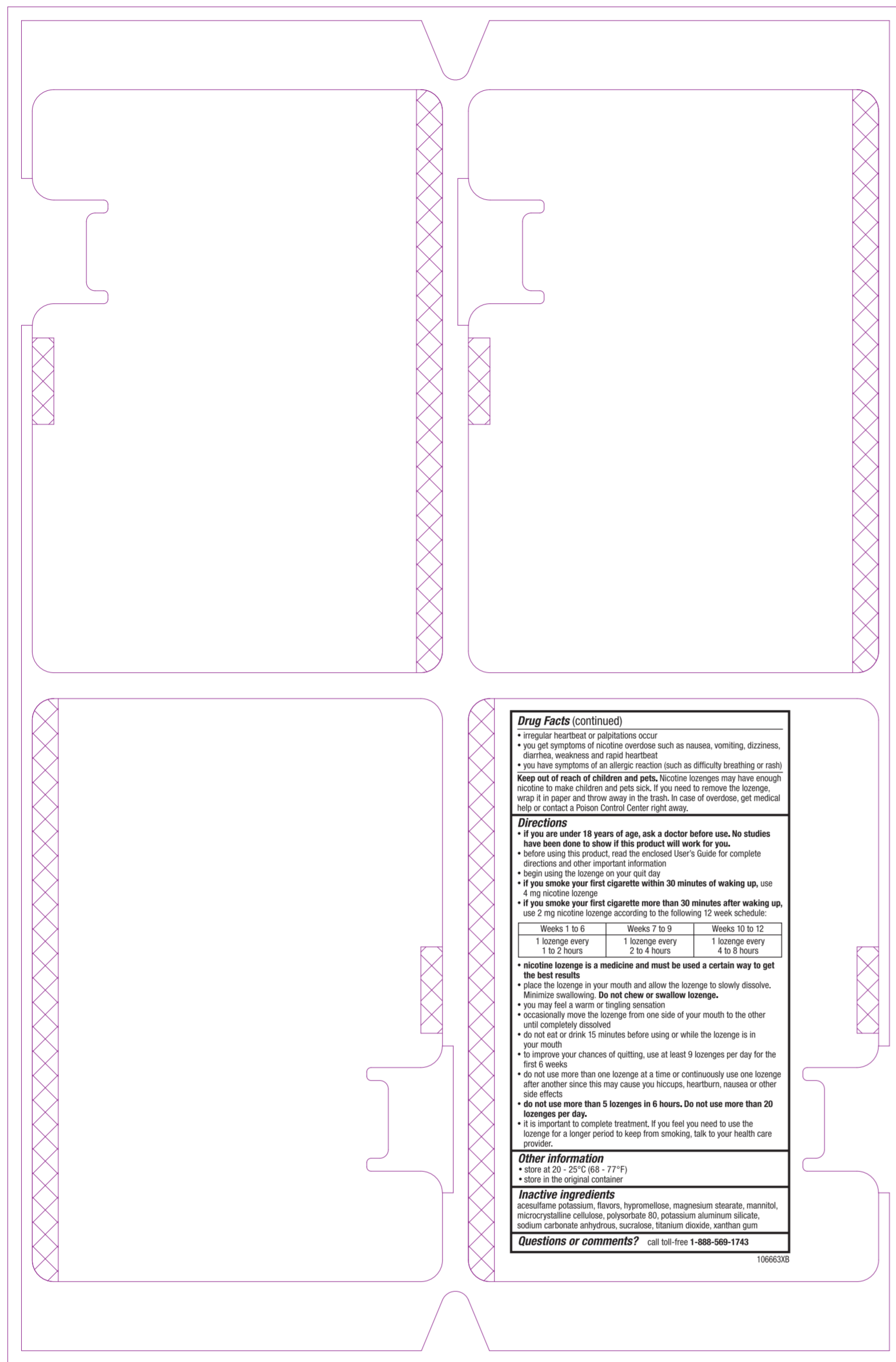
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DRUG FACTS CONTINUED	N/A
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DESCRIPTIONS/BODY TEXT	7 pt.
LEADING	8 pt.
# OF CHARACTERS PER INCH	N/A
BULLETS	7 pt.
SPACE BEFORE BULLET	N/A
DARTS/ELLS, HORIZONTALS	N/A
SPACE BETWEEN HORIZONTALS AND BOX END	N/A
STARTING OF KENTY WHAT IT GO Vertical	N/A
STATEMENT OF KENTY WHAT IT GO Horizontal	15.7 pt.



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BARLINES, HAIRLINES	N/A
SPACE BETWEEN HAIRLINES AND BOX END	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Vertical	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Horizontal	10 pt



**Drug Facts (continued)**

- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

**Keep out of reach of children and pets.** Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove the lozenge, wrap it in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- If you are under 18 years of age, ask a doctor before use. No studies have been done to show if this product will work for you.**
- before using this product, read the enclosed User's Guide for complete directions and other important information
- begin using the lozenge on your quit day
- if you smoke your first cigarette within 30 minutes of waking up,** use 4 mg nicotine lozenge
- if you smoke your first cigarette more than 30 minutes after waking up,** use 2 mg nicotine lozenge according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 lozenge every 1 to 2 hours	1 lozenge every 2 to 4 hours	1 lozenge every 4 to 8 hours

- nicotine lozenge is a medicine and must be used a certain way to get the best results**
- place the lozenge in your mouth and allow the lozenge to slowly dissolve. Minimize swallowing. **Do not chew or swallow lozenges.**
- you may feel a warm or tingling sensation
- occasionally move the lozenge from one side of your mouth to the other until completely dissolved
- do not eat or drink 15 minutes before using or while the lozenge is in your mouth
- to improve your chances of quitting, use at least 9 lozenges per day for the first 6 weeks
- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccups, heartburn, nausea or other side effects
- do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.**
- it is important to complete treatment. If you feel you need to use the lozenge for a longer period to keep from smoking, talk to your health care provider.

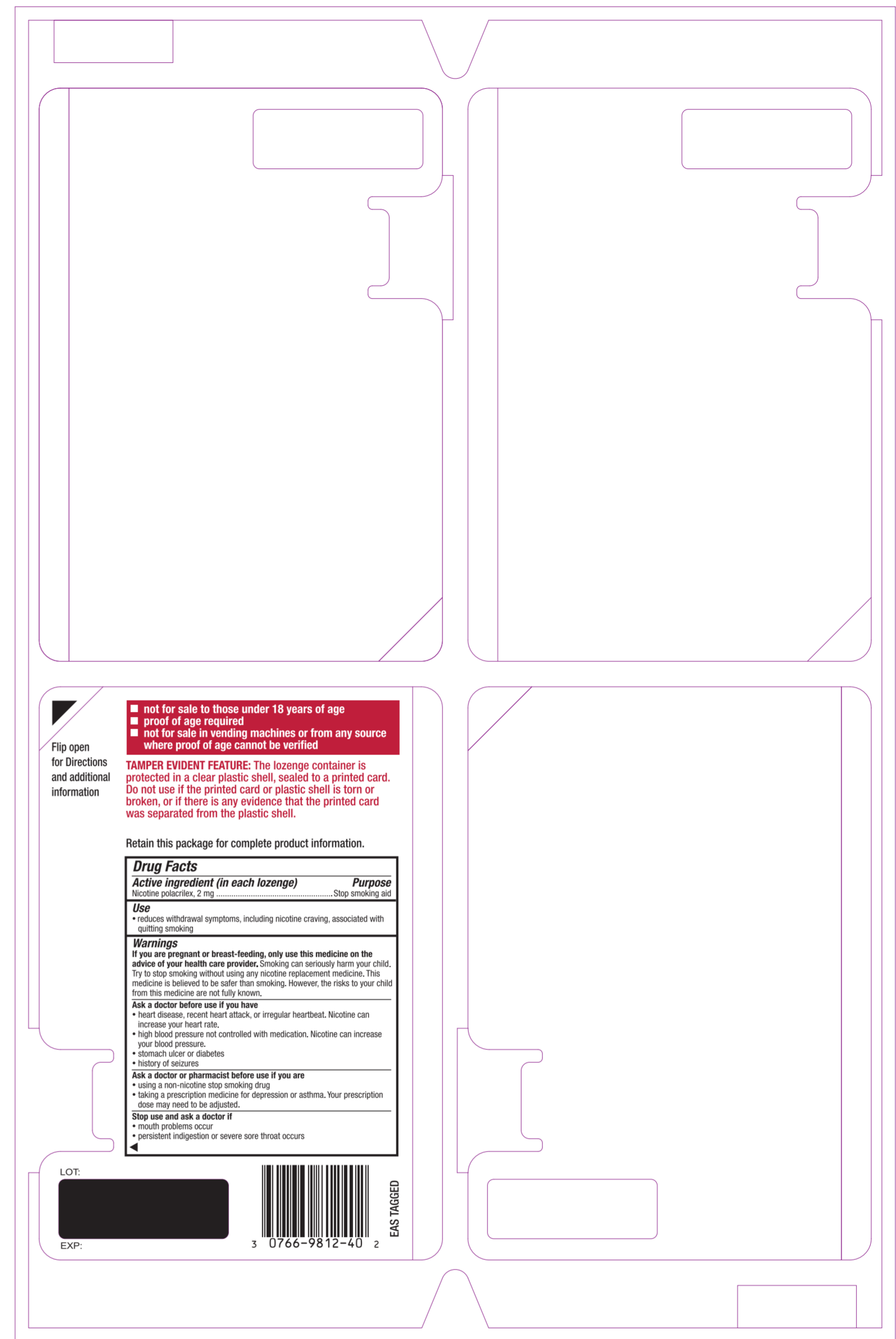
**Other information**

- store at 20° - 25° C (68° - 77° F)
- store in the original container

**Inactive ingredients**  
acesulfame potassium, flavors, hydroxypropylcellulose, magnesium stearate, mannitol, microcrystalline cellulose, polyorbital 80, potassium aluminum silicate, sodium carbonate anhydrous, sucralose, titanium dioxide, xanthan gum

**Questions or comments?** call toll-free 1-888-569-1743

106663XB



Flip open for Directions and additional information

**not for sale to those under 18 years of age**  
**proof of age required**  
**not for sale in vending machines or from any source where proof of age cannot be verified**

**TAMPER EVIDENT FEATURE:** The lozenge container is protected in a clear plastic shell, sealed to a printed card. Do not use if the printed card or plastic shell is torn or broken, or if there is any evidence that the printed card was separated from the plastic shell.

Retain this package for complete product information.

**Drug Facts**

Active ingredient (in each lozenge)	Purpose
Nicotine polacrifex, 2 mg	Stop smoking aid

**Use**

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

**Warnings**

**If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider.** Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

**Ask a doctor before use if you have**

- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- stomach ulcer or diabetes
- history of seizures

**Ask a doctor or pharmacist before use if you are**

- using a non-nicotine stop smoking drug
- taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

**Stop use and ask a doctor if**

- mouth problems occur
- persistent indigestion or severe sore throat occurs

LOT: [Redacted]

EXP: [Redacted]

3 0766-9812-40 2

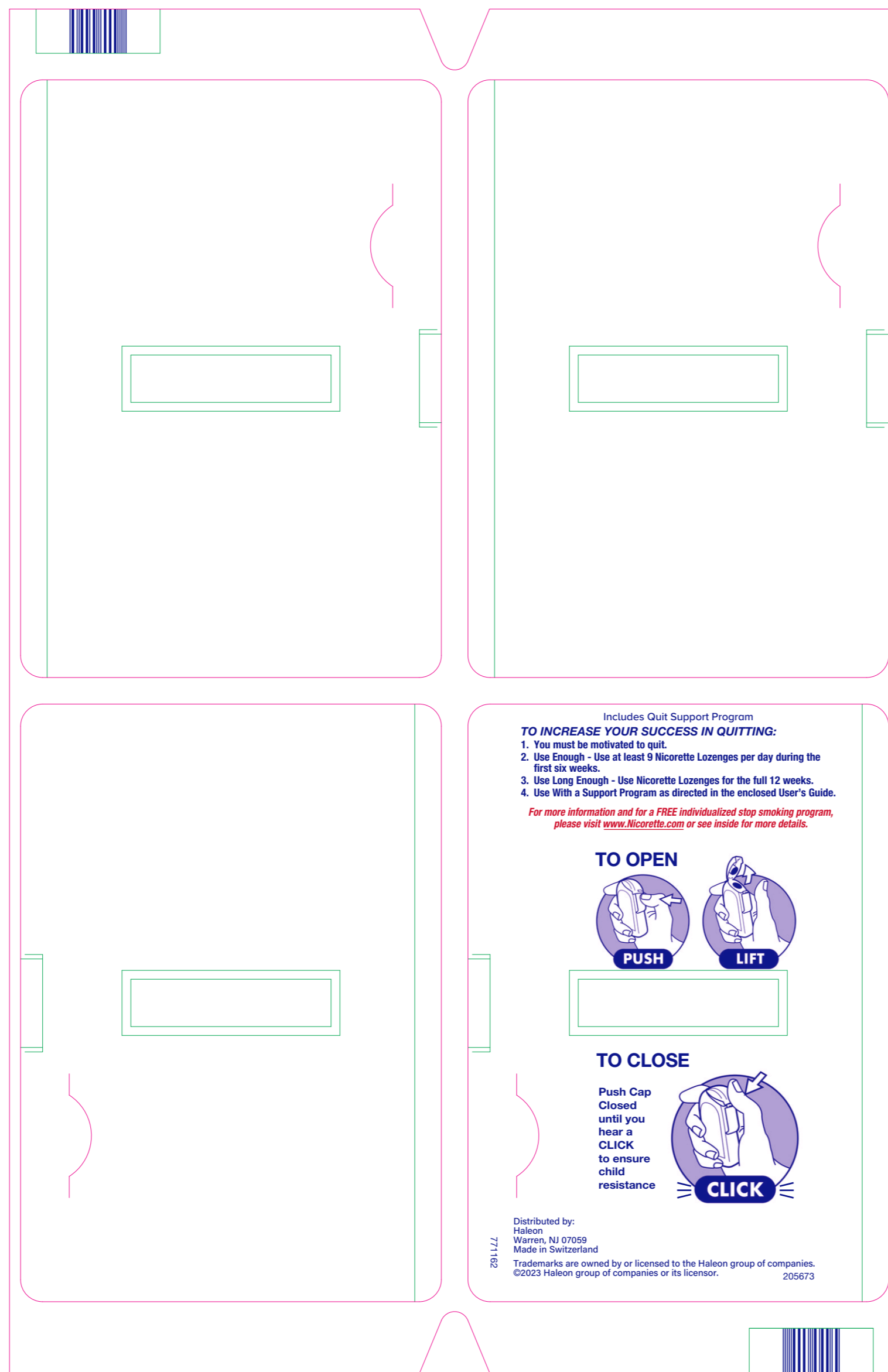
EAS TAGGED

Clean\_106663XB

(b) (4)

Drug Facts Info		
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<b>Drug Facts (continued)</b>	Font Name: Helvetica Neue LT Std 77 Bold Condensed Oblique/ Helvetica Neue LT Std 57 Condensed	8 point type
<b>Headings</b>	Font Name: Helvetica Neue LT Std 77 Bold Condensed Oblique	8 point type
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<b>Bullets</b>	Font Name: Helvetica Neue LT Std 55 Roman	5 point type
<b>Bullets on same lines: end of statement separated from bulleted statement by two ems</b>		Yes
<b>Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box</b>		Yes
<b>Tracking</b>	0	Horizontal Scale: 97%-100%
<b>Leading (Minimum space in body copy of Drug Facts)</b>	6.5 pt.	Maximum Characters/Inch: 35
<b>Barlines</b>	1.5 pt.	Hairlines 0.50 pt.

INTERLEAVED 2 OF 5 CODE REF. IS: 771162

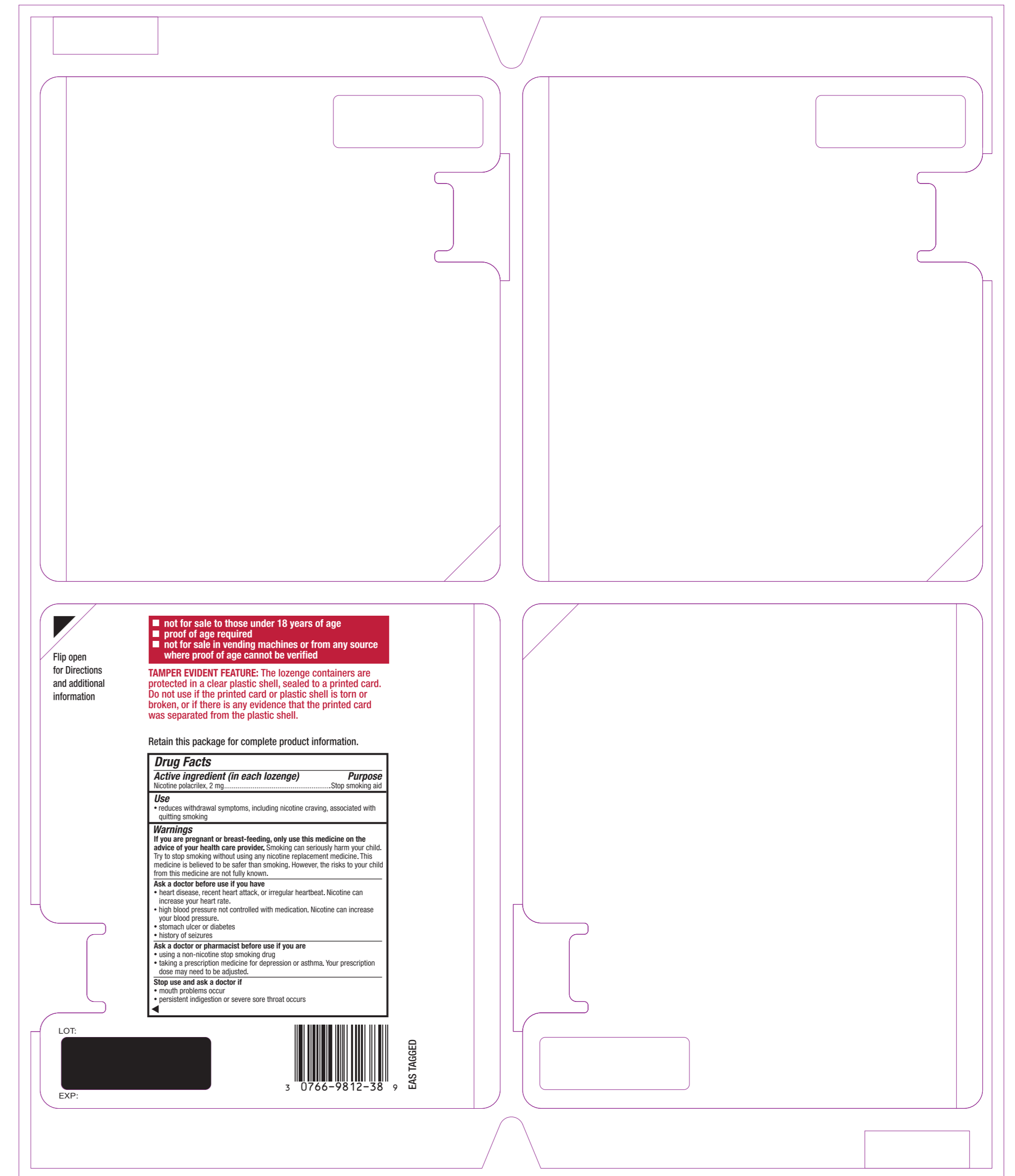
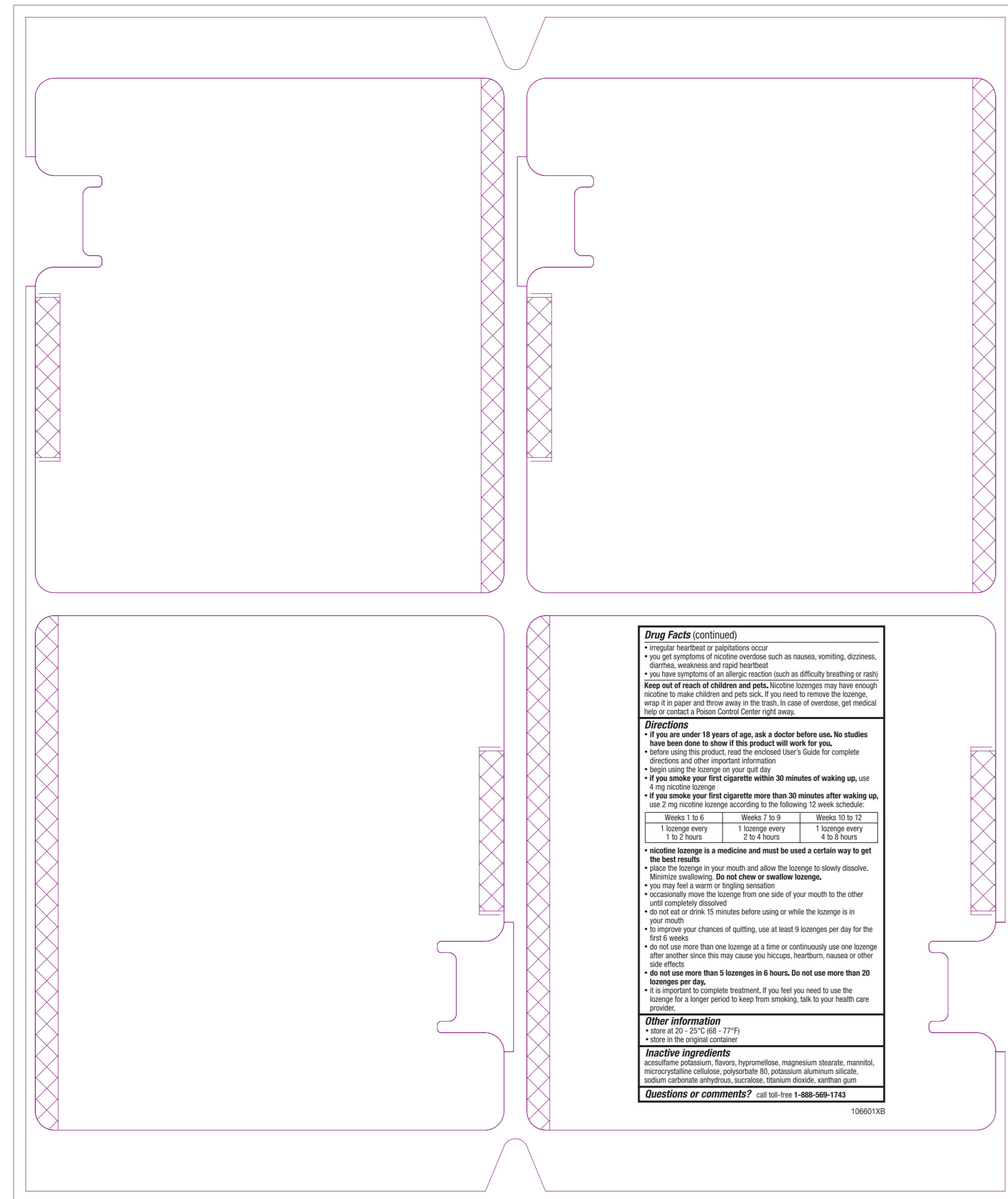


INTERLEAVED 2 OF 5 CODE REF. IS: 771162



**REGULATORY LEGEND**

	Actual Size
DRUG FACTS TITLE	N/A
DRUG FACTS CONTINUED	N/A
HEADINGS	7.5 pt.
SUBHEADINGS/BODY TEXT	7 pt.
LEADING	8 pt.
# OF CHARACTERS PER INCH	N/A
BULLETS	N/A
SPACE BEFORE BULLET	N/A
BARLINES, HAIRLINES	N/A
SPACE BETWEEN HAIRLINES AND BOX END	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Vertical	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Horizontal	19.9 pt.



**Drug Facts (continued)**

- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

**Keep out of reach of children and pets.** Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove the lozenge, wrap it in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- **if you are under 18 years of age, ask a doctor before use. No studies have been done to show if this product will work for you.**
- before using this product, read the enclosed User's Guide for complete directions and other important information
- begin using the lozenge on your quit day
- **if you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine lozenge**
- **if you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine lozenge according to the following 12 week schedule:**

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 lozenge every 1 to 2 hours	1 lozenge every 2 to 4 hours	1 lozenge every 4 to 8 hours

- **nicotine lozenge is a medicine and must be used a certain way to get the best results**
- place the lozenge in your mouth and allow the lozenge to slowly dissolve. Minimize swallowing. **Do not chew or swallow lozenge.**
- you may feel a warm or tingling sensation
- occasionally move the lozenge from one side of your mouth to the other until completely dissolved
- do not eat or drink 15 minutes before using or while the lozenge is in your mouth
- to improve your chances of quitting, use at least 9 lozenges per day for the first 6 weeks
- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccups, heartburn, nausea or other side effects
- **do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.**
- it is important to complete treatment. If you feel you need to use the lozenge for a longer period to keep from smoking, talk to your health care provider.

**Other information**

- store at 20 - 25°C (68 - 77°F)
- store in the original container

**Inactive ingredients**  
saccharin potassium, flavors, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, polyorbate 80, potassium aluminum silicate, sodium carbonate anhydrous, sucralose, titanium dioxide, xanthan gum

**Questions or comments?** call toll-free 1-888-969-1743

106601XB

**not for sale to those under 18 years of age**  
**proof of age required**  
**not for sale in vending machines or from any source where proof of age cannot be verified**

**TAMPER EVIDENT FEATURE:** The lozenge containers are protected in a clear plastic shell, sealed to a printed card. Do not use if the printed card or plastic shell is torn or broken, or if there is any evidence that the printed card was separated from the plastic shell.

Retain this package for complete product information.

**Drug Facts**

Active ingredient (in each lozenge)	Purpose
Nicotine polacrifin, 2 mg	Stop smoking aid

**Use**

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

**Warnings**

**If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider.** Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

**Ask a doctor before use if you have**


- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- stomach ulcer or diabetes
- history of seizures


**Ask a doctor or pharmacist before use if you are**


- using a non-nicotine stop smoking drug
- taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

**Stop use and ask a doctor if**

- mouth problems occur
- persistent indigestion or severe sore throat occurs

LOT: 

EXP: 

 3 0766-9812-38 9

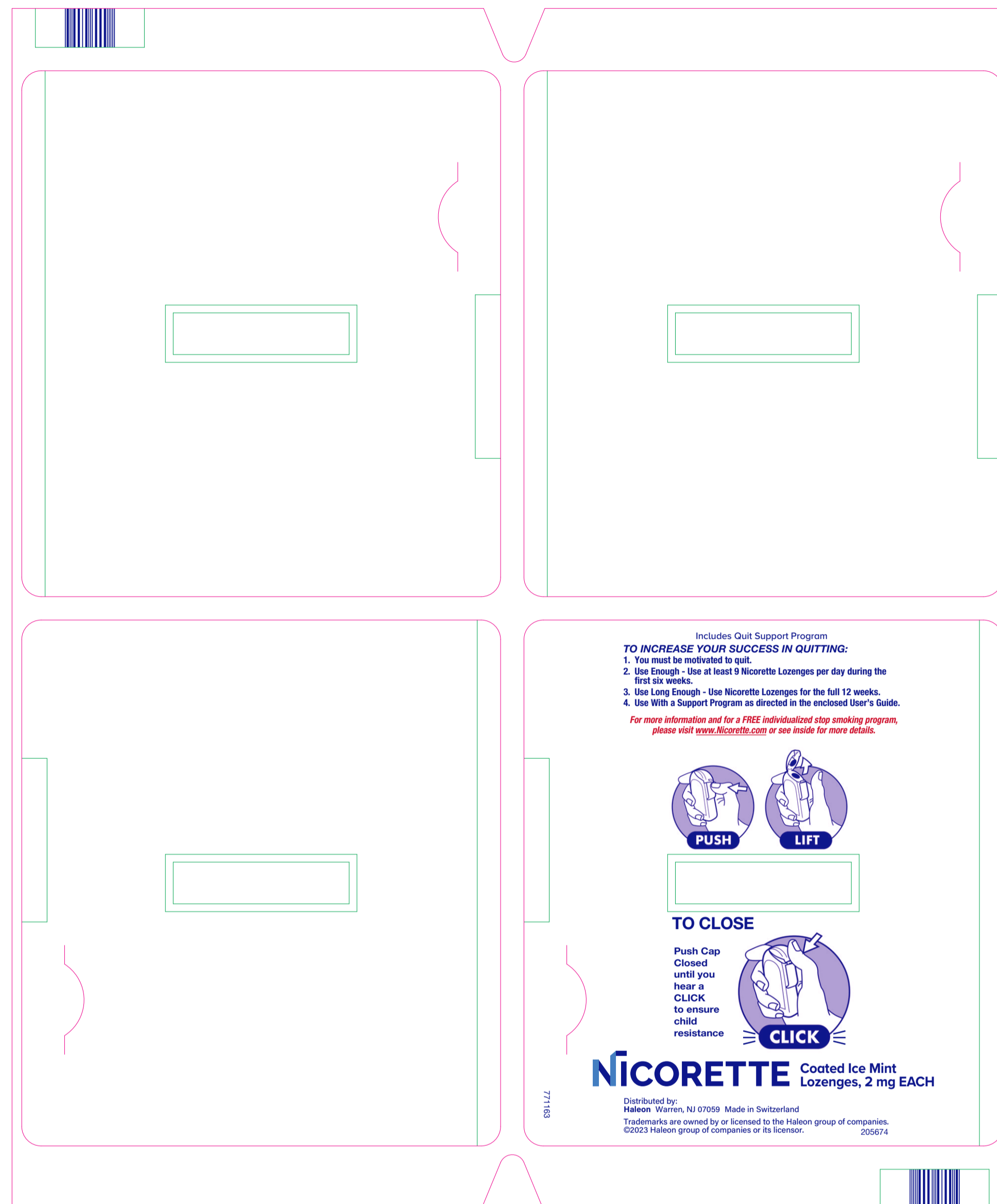
EAS TAGGED

Clean\_106601XB

(b) (4)

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Body text	Font Name: Helvetica Neue LT Std 57 Condensed / Helvetica Neue LT Std 77 Bold Condensed	6 point type
Bullets	Font Name: Helvetica Neue LT Std 55 Roman	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		Yes
Spacing of the hair lines from edge of box—i.e. Minimum of 2 spaces either side of Drug Fact Box		Yes
Tracking	0	Horizontal Scale: 97%-100%
Leading (Minimum space in body copy of Drug Facts)	6.5 pt.	Maximum Characters/Inch: 35
Barlines	1.5 pt.	Harlines: 0.50 pt.

INTERLEAVED 2 OF 5 CODE REF IS:  
771165



INTERLEAVED 2 OF 5 CODE REF IS:  
771165



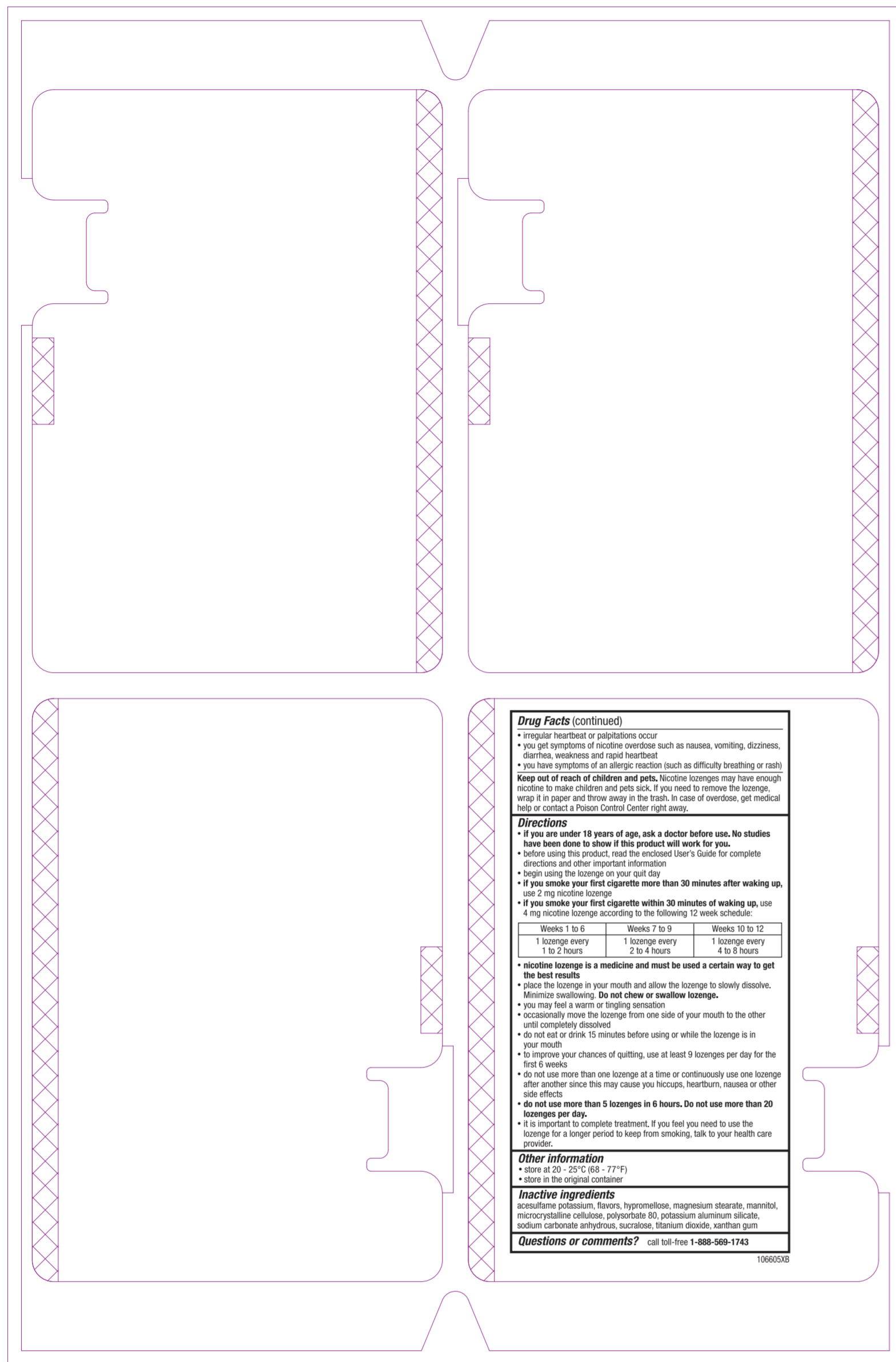
**REGULATORY LEGEND**

	Actual Size
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DRUG FACTS CONTINUED	N/A
HEADINGS	7.5 pt.
SUBHEADINGS/BODY TEXT	7 pt.
LEADING	8 pt.
# OF CHARACTERS PER INCH	N/A
BULLETS	N/A
SPACE BEFORE BULLET	N/A
BARLINES, HAIRLINES	N/A
SPACE BETWEEN HAIRLINES AND BOX END	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Vertical	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Horizontal	24.9 pt.



### REGULATORY LEGEND

	Actual Size
DRUG FACTS TITLE	N/A
DRUG FACTS CONTINUED	N/A
HEADINGS	N/A
SUBHEADINGS/BODY TEXT	N/A
LEADING	N/A
# OF CHARACTERS PER INCH	N/A
BULLETS	N/A
SPACE BEFORE BULLET	N/A
BARLINES, HAIRLINES	N/A
SPACE BETWEEN HAIRLINES AND BOX END	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Vertical	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Horizontal	10 pt



**Drug Facts (continued)**

- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

**Keep out of reach of children and pets.** Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove the lozenge, wrap it in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- **If you are under 18 years of age, ask a doctor before use. No studies have been done to show if this product will work for you.**
- before using this product, read the enclosed User's Guide for complete directions and other important information
- begin using the lozenge on your quit day
- **if you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine lozenge**
- **if you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine lozenge according to the following 12 week schedule:**

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 lozenge every 1 to 2 hours	1 lozenge every 2 to 4 hours	1 lozenge every 4 to 8 hours

- **nicotine lozenge is a medicine and must be used a certain way to get the best results**
- place the lozenge in your mouth and allow the lozenge to slowly dissolve. Minimize swallowing. **Do not chew or swallow lozenges.**
- you may feel a warm or tingling sensation
- occasionally move the lozenge from one side of your mouth to the other until completely dissolved
- do not eat or drink 15 minutes before using or while the lozenge is in your mouth
- to improve your chances of quitting, use at least 9 lozenges per day for the first 6 weeks
- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccups, heartburn, nausea or other side effects
- **do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.**
- it is important to complete treatment. If you feel you need to use the lozenge for a longer period to keep from smoking, talk to your health care provider.

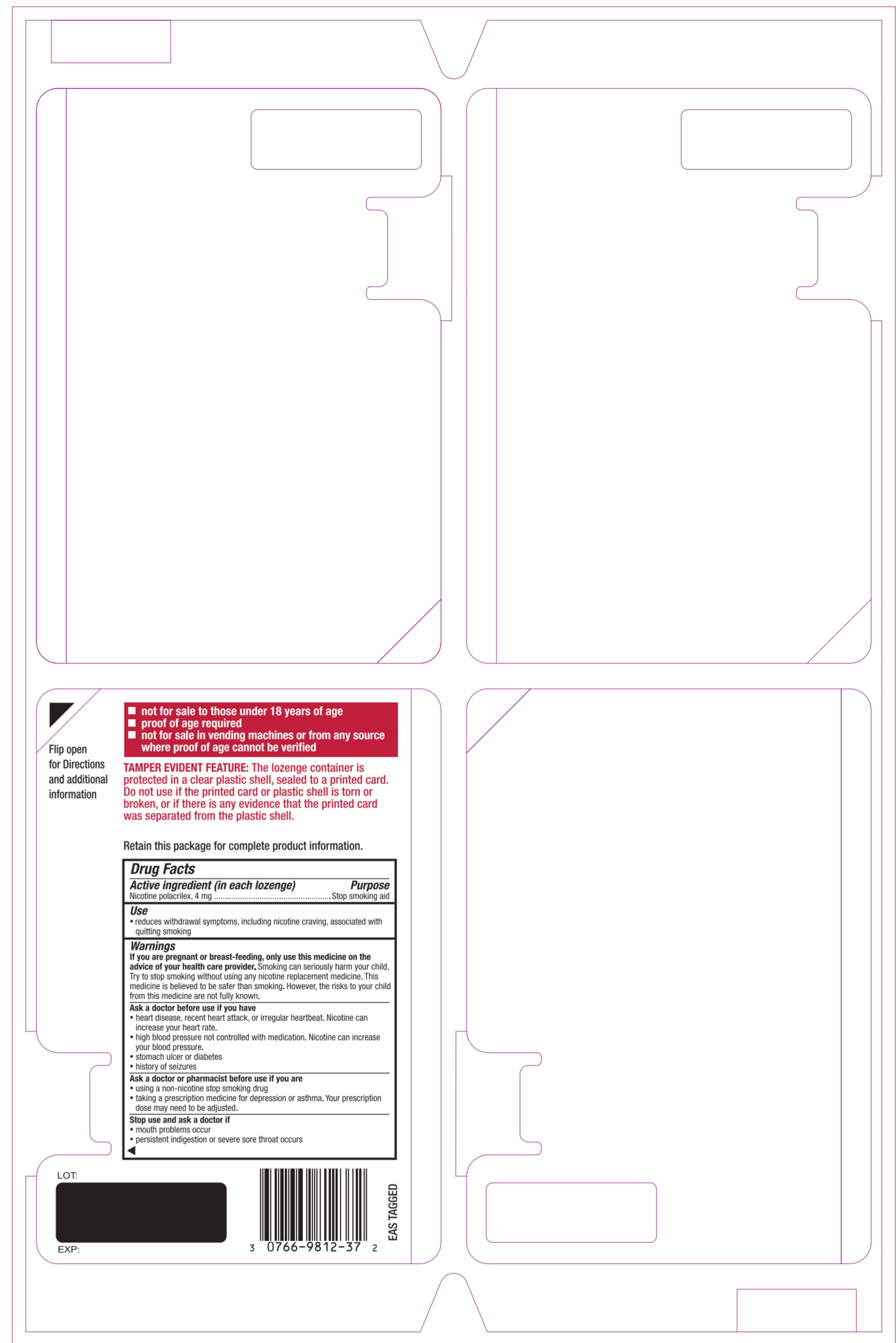
**Other information**

- store at 20° - 25° C (68° - 77° F)
- store in the original container

**Inactive ingredients**  
acesulfame potassium, flavors, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, polyorbate 80, potassium aluminum silicate, sodium carbonate anhydrous, sucralose, titanium dioxide, xanthan gum

**Questions or comments?** call toll-free 1-888-569-1743

106605XB



Flip open for Directions and additional information

not for sale to those under 18 years of age  
 proof of age required  
 not for sale in vending machines or from any source where proof of age cannot be verified

**TAMPER EVIDENT FEATURE:** The lozenge container is protected in a clear plastic shell, sealed to a printed card. Do not use if the printed card or plastic shell is torn or broken, or if there is any evidence that the printed card was separated from the plastic shell.

Retain this package for complete product information.

**Drug Facts**

**Active ingredient (in each lozenge)** Nicotine poliacetate, 4 mg **Purpose** Stop smoking aid

**Use**

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

**Warnings**

**If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider.** Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

**Ask a doctor before use if you have**

- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- stomach ulcer or diabetes
- history of seizures

**Ask a doctor or pharmacist before use if you are**

- using a non-nicotine stop smoking drug
- taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

**Stop use and ask a doctor if**

- mouth problems occur
- persistent indigestion or severe sore throat occurs

LOT: [Redacted]

EXP: [Redacted]

3 0766-9812-37 2

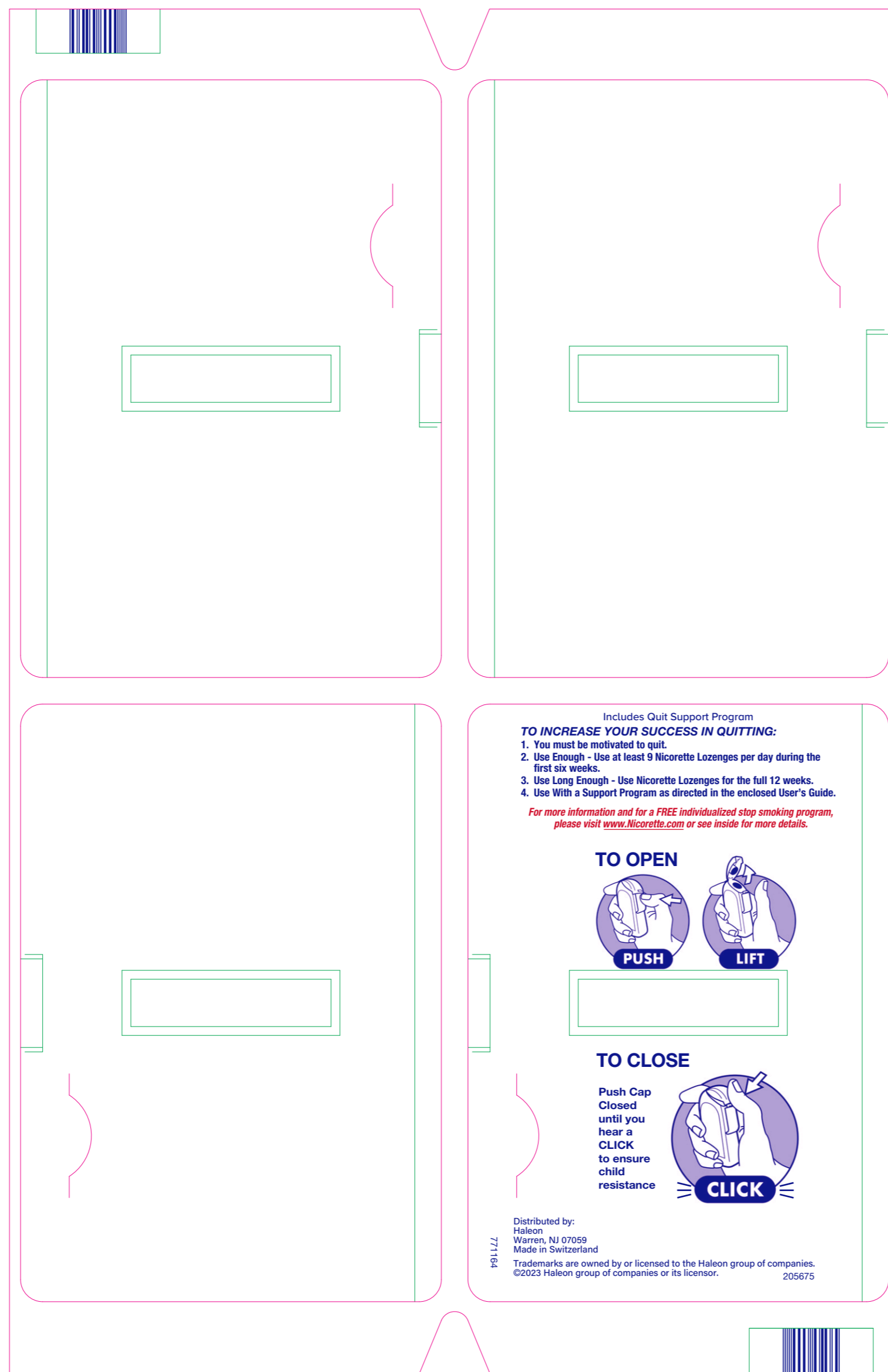
EAS TAGGED

Clean\_106605XB

(b) (4)

Drug Facts Info			
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<b>Headings</b>	Font Name: Helvetica Neue LT Std 77 Bold Condensed Oblique		8 point type
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<b>Bullets</b>	Font Name: Helvetica Neue LT Std 55 Roman		5 point type
<b>Bullets on same lines: end of statement separated from bulleted statement by two ems</b>			Yes
<b>Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box</b>			Yes
<b>Tracking</b>	0	<b>Horizontal Scale:</b>	97%-100%
<b>Leading (Minimum space in body copy of Drug Facts)</b>	6.5 pt.	<b>Maximum Characters/Inch:</b>	35
<b>Barlines</b>	1.5 pt.	<b>Hairlines</b>	0.50 pt.

INTERLEAVED 2 OF 5 CODE REF. IS: 771164

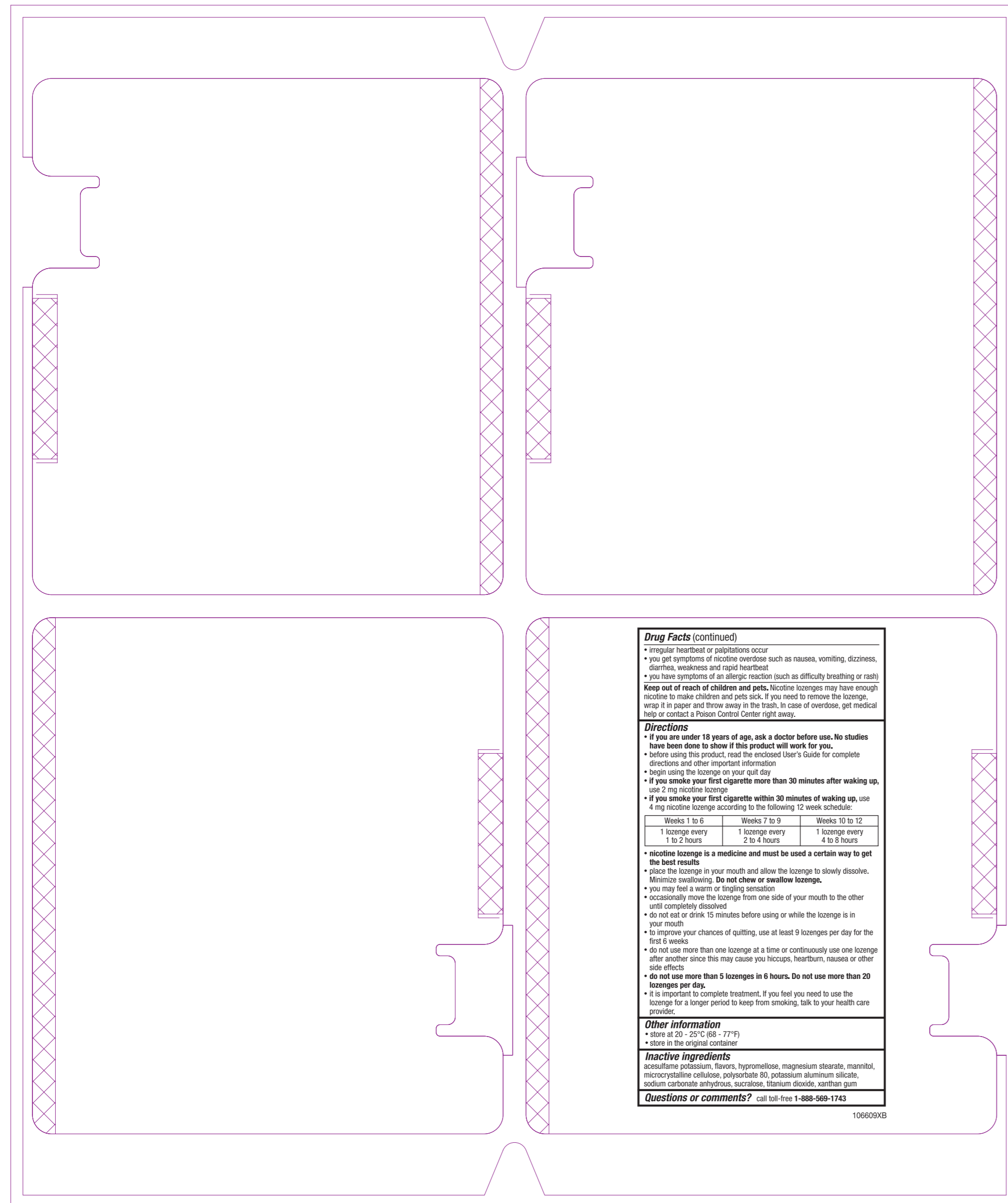


INTERLEAVED 2 OF 5 CODE REF. IS: 771164



**REGULATORY LEGEND**

	Actual Size
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DRUG FACTS CONTINUED	N/A
HEADINGS	7.5 pt
SUBHEADINGS/BODY TEXT	7 pt
LEADING	8 pt
# OF CHARACTERS PER INCH	N/A
BULLETS	N/A
SPACE BEFORE BULLET	N/A
BARLINES, HAIRLINES	N/A
SPACE BETWEEN HAIRLINES AND BOX END	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Vertical	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Horizontal	19.9 pt.



**Drug Facts (continued)**

- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

**Keep out of reach of children and pets.** Nicotine lozenges may have enough nicotine to make children and pets sick. If you need to remove the lozenge, wrap it in paper and throw away in the trash. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- if you are under 18 years of age, ask a doctor before use. No studies have been done to show if this product will work for you.
- before using this product, read the enclosed User's Guide for complete directions and other important information
- begin using the lozenges on your quit day
- if you smoke your first cigarette more than 30 minutes after waking up, use 2 mg nicotine lozenges
- if you smoke your first cigarette within 30 minutes of waking up, use 4 mg nicotine lozenges according to the following 12 week schedule:

Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 lozenge every 1 to 2 hours	1 lozenge every 2 to 4 hours	1 lozenge every 4 to 8 hours

- nicotine lozenge is a medicine and must be used a certain way to get the best results
- place the lozenge in your mouth and allow the lozenge to slowly dissolve. Minimize swallowing. Do not chew or swallow lozenge.
- you may feel a warm or tingling sensation
- occasionally move the lozenge from one side of your mouth to the other until completely dissolved
- do not eat or drink 15 minutes before using or while the lozenge is in your mouth
- to improve your chances of quitting, use at least 9 lozenges per day for the first 6 weeks
- do not use more than one lozenge at a time or continuously use one lozenge after another since this may cause you hiccups, heartburn, nausea or other side effects
- do not use more than 5 lozenges in 6 hours. Do not use more than 20 lozenges per day.
- it is important to complete treatment. If you feel you need to use the lozenge for a longer period to keep from smoking, talk to your health care provider.

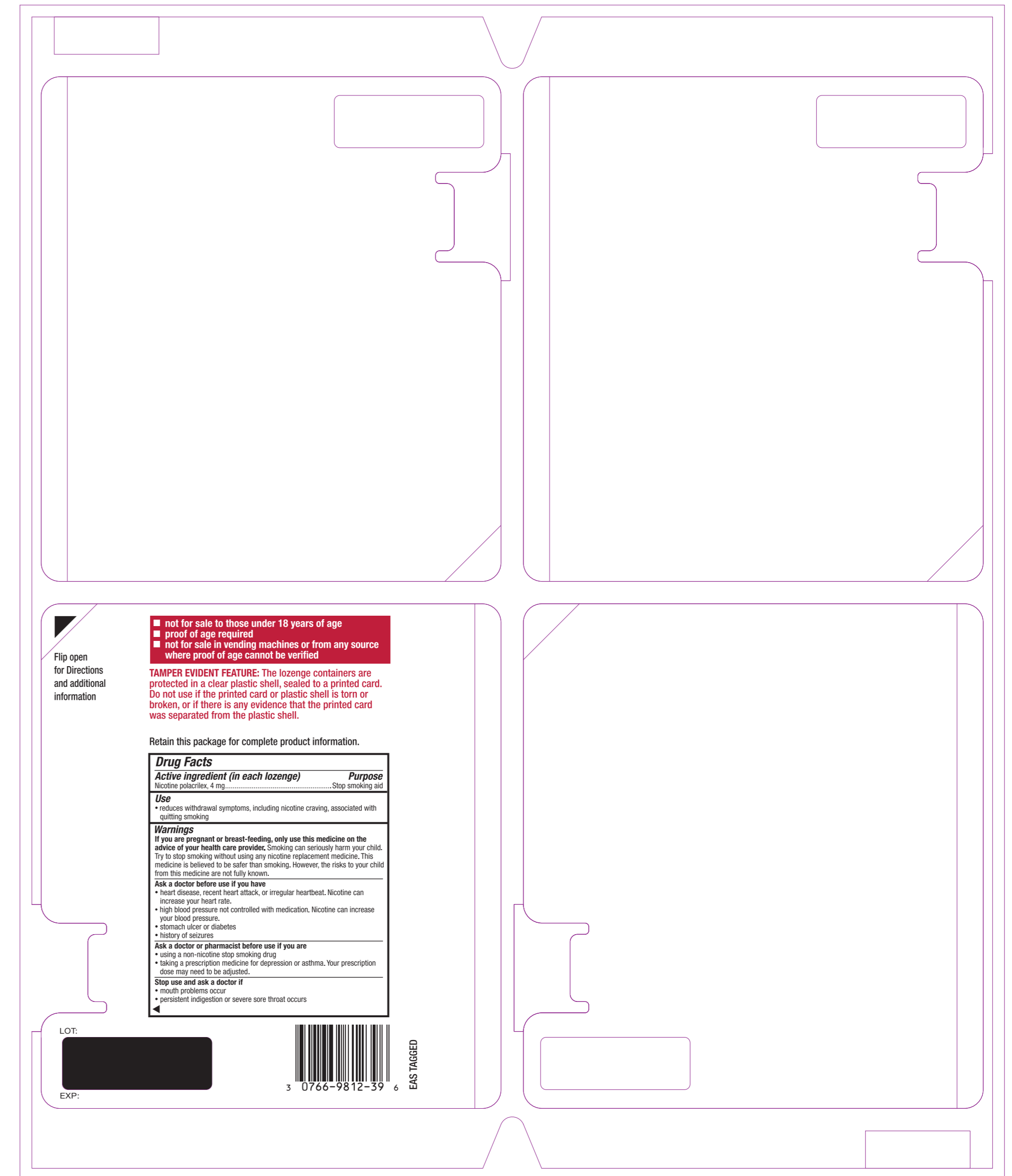
**Other information**

- store at 20° - 25°C (68° - 77°F)
- store in the original container

**Inactive ingredients**  
saccharine potassium, flavors, hydroxypropylcellulose, magnesium stearate, mannitol, microcrystalline cellulose, polyorbate 80, potassium aluminum silicate, sodium carbonate anhydrous, sucralose, titanium dioxide, xanthan gum

**Questions or comments?** call toll-free 1-888-569-1743

106609XB



■ not for sale to those under 18 years of age  
■ proof of age required  
■ not for sale in vending machines or from any source where proof of age cannot be verified

**TAMPER EVIDENT FEATURE:** The lozenge containers are protected in a clear plastic shell, sealed to a printed card. Do not use if the printed card or plastic shell is torn or broken, or if there is any evidence that the printed card was separated from the plastic shell.

Retain this package for complete product information.

**Drug Facts**

Active ingredient (in each lozenge)	Purpose
Nicotine polacrifex, 4 mg	.....Stop smoking aid

**Use**

- reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

**Warnings**

If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

**Ask a doctor before use if you have**

- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- stomach ulcer or diabetes
- history of seizures

**Ask a doctor or pharmacist before use if you are**

- using a non-nicotine stop smoking drug
- taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

**Stop use and ask a doctor if**

- mouth problems occur
- persistent indigestion or severe sore throat occurs

LOT:



EXP:



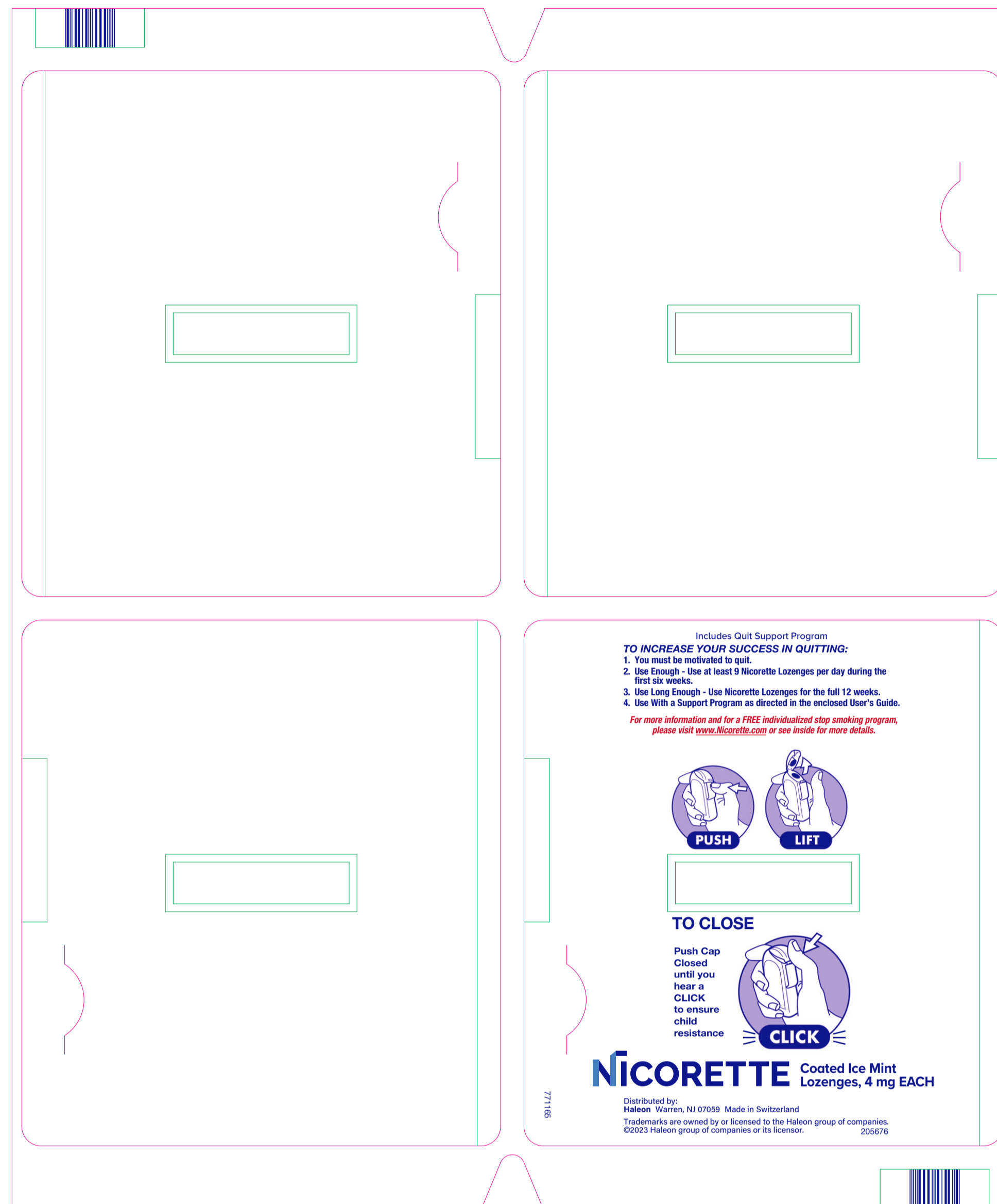
EAS TAGGED

Clean\_106609XB

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Bullets	Font Name: Helvetica Neue LT Std 55 Roman	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		Yes
Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box		Yes
Tracking	0	Horizontal Scale: 97%-100%
Leading (Minimum space in body copy of Drug Facts)	6.5 pt.	Maximum Characters/Inch: 35
Barlines	1.5 pt.	Hairlines 0.50 pt.

INTERLEAVED 2 OF 5 CODE REF IS:  
771165



INTERLEAVED 2 OF 5 CODE REF IS:  
771165

**REGULATORY LEGEND**

	Actual Size
DRUG FACTS TITLE	N/A
DRUG FACTS CONTINUED	N/A
HEADINGS	7.5 pt.
SUBHEADINGS/BODY TEXT	7 pt.
LEADING	8 pt.
# OF CHARACTERS PER INCH	N/A
BULLETS	N/A
SPACE BEFORE BULLET	N/A
BARLINES, HAIRLINES	N/A
SPACE BETWEEN HAIRLINES AND BOX END	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Vertical	N/A
STATEMENT OF IDENTITY (WHAT IT IS) Horizontal	24.9 pt.

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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NUSHIN F TODD  
09/06/2024 02:07:26 PM