

IMPORTANT INFORMATION FOR ALL PATIENTS:
It is important for your health that you read all the information you received with this prescription and from your doctor.

This package provides reminders of important safety facts about Absorica LD, but it does not contain all the information you need to know. It is important for you to know how to take Absorica LD correctly and what side effects to watch for.

Read all the information you get about Absorica LD from your doctor and pharmacist, including the **Medication Guide** provided with this package.

You should read, understand and sign a Patient Information/Informed Consent form before you take Absorica LD. Contact your doctor if you have not signed this form (male patients and female patients who cannot get pregnant must sign 1 form and female patients who can get pregnant must sign 2 forms).

Never share Absorica LD because it can cause serious side effects including **severe birth defects**.

Before you start taking Absorica LD, tell your doctor if you:

- Are currently taking an oral or injected corticosteroid or an anticonvulsant (seizure) medication.
- Take part in sports where you are more likely to break a bone.
- Have mental problems, anorexia nervosa (a type of eating disorder), back pain, a history of problems with healing of bone fractures, or problems with bone metabolism.



Special Warning for Female Patients

Absorica LD causes serious birth defects. Do NOT take Absorica LD if you are pregnant.

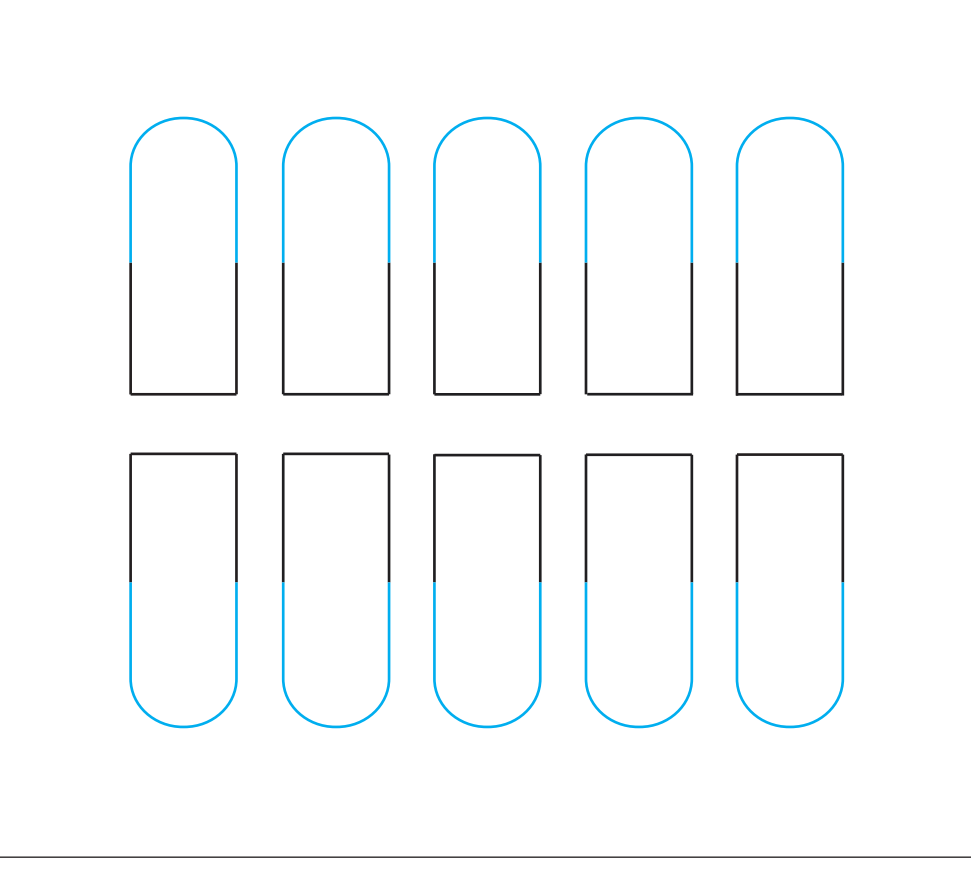
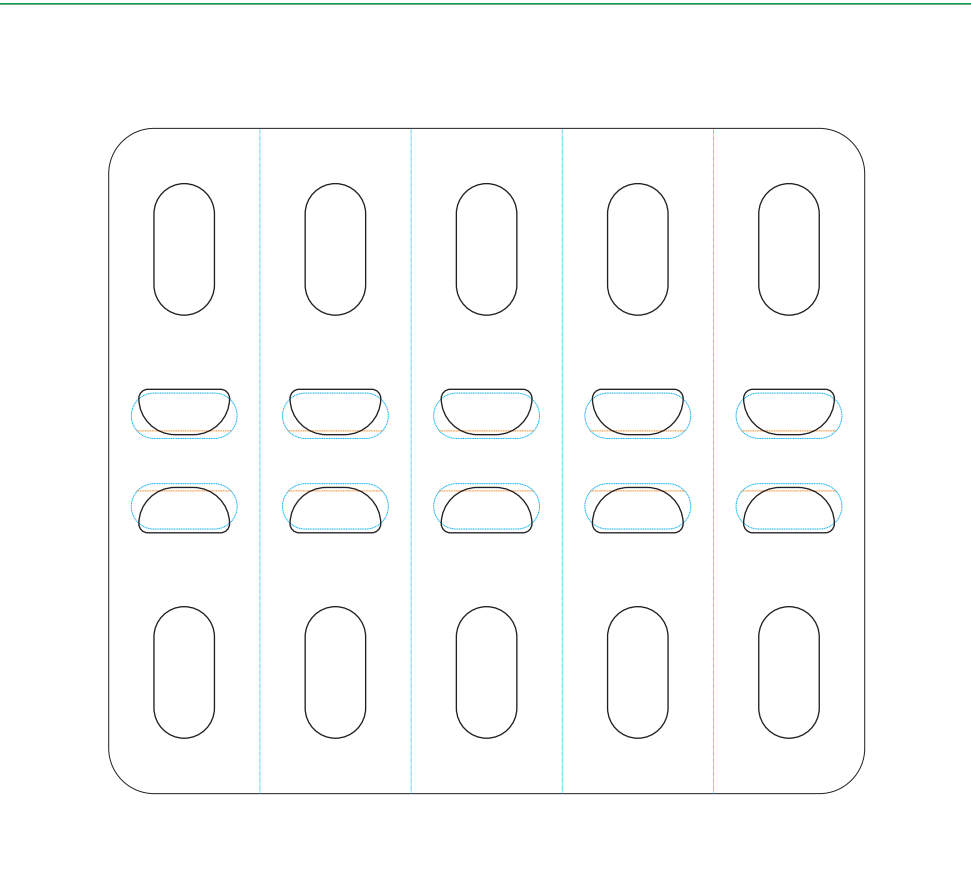
It is very important for you to read and understand the information about preventing pregnancy found in this package, the Medication Guide, and the materials given to you by your doctor. It is very important for you to interact with the iPLEDGE system to answer questions about program requirements and view the video at your doctor's office. If you do not have the Medication Guide, and the patient booklets about pregnancy prevention, don't start taking Absorica LD. Call your doctor.

Most people have further questions after reading so much important information about pregnancy prevention and birth defects. If there is anything you are not sure about, do **not** take Absorica LD until your questions have been answered by your doctor.

Mental problems and suicide
Some patients have become depressed or developed other serious mental problems while they were taking isotretinoin or shortly after stopping isotretinoin. Some patients taking isotretinoin have had thoughts of ending their own lives (suicidal thoughts). Some people have tried to end their own lives (attempted suicide) and some people have ended their own lives (committed suicide). There have been reports of patients on isotretinoin becoming aggressive or violent.

Stop taking Absorica LD and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells.
 - Lose interest in activities you once enjoyed.
 - Sleep too much or have trouble sleeping.
 - Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence).
 - Have a change in your appetite or body weight.
 - Have trouble concentrating.
 - Withdraw from your friends or family.
 - Feel like you have no energy.
 - Have feelings of worthlessness or guilt.
 - Start having thoughts about hurting yourself or taking your own life (suicidal thoughts).
 - Start acting on dangerous impulses.
 - Start seeing or hearing things that are not real.
- Tell your doctor if you or someone in your family has ever had a mental illness or if you take any medicines for a mental illness (for example, depression).
- Other serious side effects to watch for**
Stop taking Absorica LD and call your doctor if you develop any of the problems on this list or any other unusual or severe problems. If not treated, they could lead to serious health problems. Serious permanent problems do not happen often.
- Headaches, nausea, vomiting, blurred vision (increased brain pressure).
 - Severe stomach pain, diarrhea, rectal bleeding, or trouble swallowing.
 - Yellowing of your skin or eyes and/or dark urine.
 - Changes in hearing.
 - Allergic reactions (if you know you are sensitive to "parabens", tell your doctor because it is preservative in the gelatin capsule of Absorica LD).
 - Bone or muscle pain.
 - Vision changes, including trouble seeing at night (this can start suddenly, so be very careful when driving or operating any vehicle at night).
 - Persistent fever, chills, or sore throat.
- Other Important Information is found in the Medication Guide and in the booklets from your doctor:**
- Common side effects that are not serious but that you should tell your doctor about.
 - How to take Absorica LD.
 - Things to avoid during Absorica LD treatment.
 - Ways to get more information if you need it.



SAP CODE : 0000000



Card Open Size : 617 x 130 mm
Card Close Size : 118 x 13 x 130 mm

Track : A25/10/2021

PHARMACISTS: DISPENSE INTACT
PLACE PRESCRIPTION LABEL HERE

PATIENT: READ INFORMATION CAREFULLY

Attention: Absorica and Absorica LD are NOT substitutable given that the bioavailability and dosage of these products are different.

16 mg
Absorica LD™
(isotretinoin) Capsules, USP
Each capsule contains 16 mg isotretinoin, USP (Prescription Pack)
10 Capsules

NDC 10631-003-69
Rx only
Dispense with enclosed Medication Guide.
Attention Pharmacists:

FEMALE PATIENTS: DO NOT GET PREGNANT

Absorica LD Causes Serious Birth Defects
Highlights of Warning to Female Patients.
(It is important to watch the video and read all information in the materials given to you by your doctor.)

- You MUST NOT take Absorica LD if you are pregnant because any amount can cause severe birth defects, even if taken for short periods during pregnancy.
- You MUST NOT become pregnant 1 month before, during, and for 1 month after you stop taking Absorica LD.
- You will not get your first prescription for Absorica LD until there is proof you have had 2 negative pregnancy tests as instructed by your doctor (a negative test means that it does not show pregnancy) and you have interacted with the iPLEDGE system to answer questions about program requirements.
- You cannot get monthly refills for Absorica LD unless there is proof that you have had a negative pregnancy test conducted in a lab every month during Absorica LD treatment.
- Even the best methods of birth control can fail. Therefore, 2 separate, effective forms of birth control must be used at the same time for at least 1 month before, during, and for 1 month after you stop taking Absorica LD.
- Stop taking Absorica LD right away and call your doctor immediately if you have sex without birth control, miss your period or think you are pregnant while you are taking Absorica LD. If you think you are pregnant in the month after you have stopped Absorica LD treatment, call your doctor immediately.

Manufactured by: Ohm Laboratories Inc. New Brunswick, NJ 08901
Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512

SEAL TAB closure
Non Varnish Area
October 2021
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FEMALE PATIENTS: DO NOT GET PREGNANT

Very severe birth defects have occurred with isotretinoin use including:

- Severe Internal Defects:** defects that you cannot see—involving the brain (including lower IQ scores), heart, glands and nervous system.
- Severe External Defects:** defects that you can see—such as low-set, deformed or absent ears, wide-set eyes, depressed bridge of nose, enlarged head and small chin.

FIGURE A PAPER-FOIL TAB
PERFORATIONS

This package is child-resistant.
Keep out of reach of children.
STORE AT 20° C - 25° C (68° F - 77° F), EXCURSION PERMITTED BETWEEN 15° C - 30° C (59° F - 86° F) [SEE USP CONTROLLED ROOM TEMPERATURE.]
PROTECT FROM LIGHT.

**WARNING TO FEMALE PATIENTS
ABSORICA LD CAUSES SEVERE BIRTH DEFECTS.**

YOU MUST NOT TAKE ABSORICA LD IF YOU ARE PREGNANT OR MAY BECOME PREGNANT DURING TREATMENT.

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Non Varnish Area (for Lot & Exp)

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Strip

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Before you start taking Absorica LD, tell your doctor if you:

- Are currently taking an oral or injected corticosteroid or an anticonvulsant (seizure) medication.
- Take part in sports where you are more likely to break a bone.
- Have mental problems, anorexia nervosa (a type of eating disorder), back pain, a history of problems with healing of bone fractures, or problems with bone metabolism.

Absorica LD™
(isotretinoin) Capsules, USP

Special Warning for Female Patients

**CAUSES BIRTH DEFECTS
DO NOT GET PREGNANT**

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Most people have further questions after reading so much important information about pregnancy prevention and birth defects. If there is anything you are not sure about, do not take Absorica LD until your questions have been answered by your doctor.

Mental problems and suicide
Some patients have become depressed or developed other serious mental problems while they were taking isotretinoin or shortly after stopping isotretinoin. Some patients taking isotretinoin have had thoughts of ending their own lives (suicidal thoughts). Some people have tried to end their own lives (attempted suicide) and some people have ended their own lives (committed suicide). There have been reports of patients on isotretinoin becoming aggressive or violent.

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- Sleep too much or have trouble sleeping.
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- Have a change in your appetite or body weight.
- Have trouble concentrating.
- Withdraw from your friends or family.
- Feel like you have no energy.
- Have feelings of worthlessness or guilt.
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts).
- Start acting on dangerous impulses.
- Start seeing or hearing things that are not real.

Tell your doctor if you or someone in your family has ever had a mental illness or if you take any medicines for a mental illness (for example, depression).

Other serious side effects to watch for
Stop taking Absorica LD and call your doctor if you develop any of the problems on this list or any other unusual or severe problems. If not treated, they could lead to serious health problems. Serious permanent problems do not happen often.

- Headaches, nausea, vomiting, blurred vision (increased brain pressure).
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- Yellowing of your skin or eyes and/or dark urine.
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- Bone or muscle pain.
- Vision changes, including trouble seeing at night (this can start suddenly, so be very careful when driving or operating any vehicle at night).
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- Things to avoid during Absorica LD treatment.
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Non Varnish Area

PHARMACISTS:
DISPENSE INTACT.
PLACE PRESCRIPTION LABEL HERE

PATIENT: READ INFORMATION CAREFULLY

Attention: Absorica LD and Absorica LD are NOT substitutable given that the bioavailability and dosage of these products are different.

Absorica LD™
(isotretinoin) Capsules, USP
20 mg (Prescription Pack)
10 Capsules
Each capsule contains 20 mg isotretinoin, USP

Dispense with enclosed Medication Guide.
Attention Pharmacist:
NDC 10631-004-69
Rx only

FEMALE PATIENTS: DO NOT GET PREGNANT

Absorica LD Causes Serious Birth Defects

Highlights of Warning to Female Patients.
(It is important to watch the video and read all information in the materials given to you by your doctor.)

- You MUST NOT take Absorica LD if you are pregnant because any amount can cause severe birth defects, even if taken for short periods during pregnancy.
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Manufactured by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

Distributed by:
Sun Pharmaceutical
Industries, Inc.
Cranebury, NJ 08512

SEAL
TAB
closure
Non Varnish Area

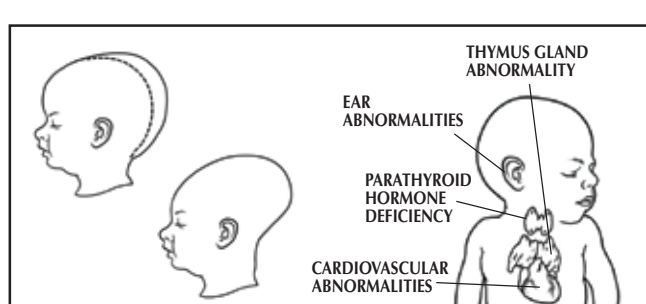
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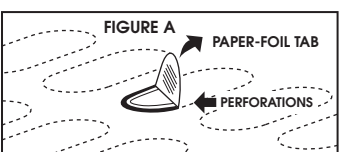
October 2021

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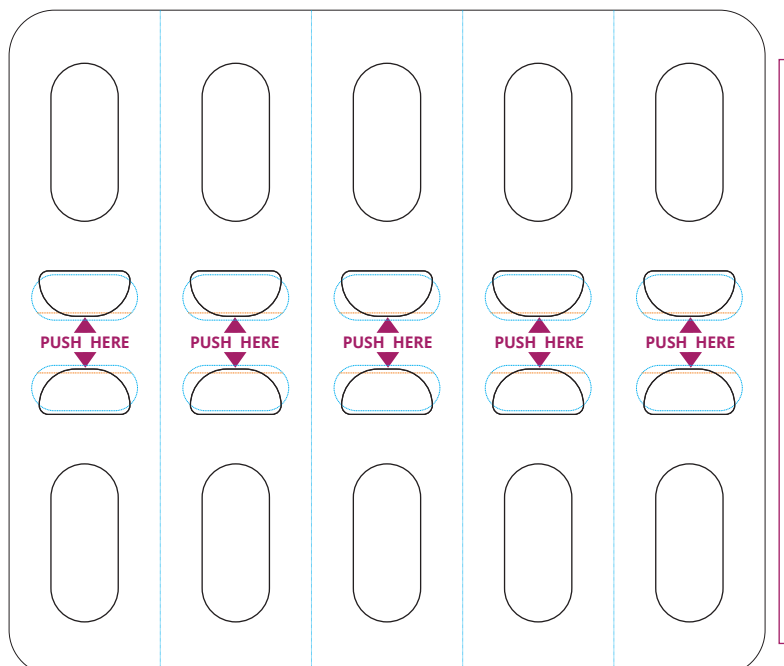




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WARNING TO FEMALE PATIENTS
ABSORICA LD CAUSES SEVERE BIRTH DEFECTS.

WARNING TO FEMALE PATIENTS: DO NOT GET PREGNANT

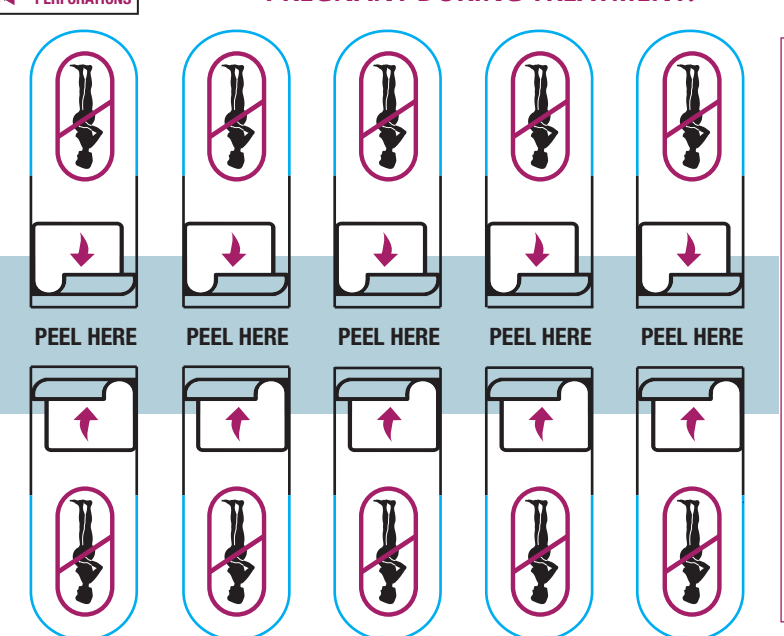


1
DIRECTIONS FOR REMOVING EACH CAPSULE:
1. Push the cap to the right to Step 2. Turn the cap side.

YOU MUST NOT TAKE ABSORICA LD IF YOU ARE PREGNANT OR MAY BECOME PREGNANT DURING TREATMENT.


2
Peel the cap along the perforations in the blister pack to remove the cap. Do not separate the cap from the blister pack. See Figure C on reverse side.

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3
Keep package intact so that it will continue to provide the important information you should know as you take Absorica LD.

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Non Varnish Area
(for Lot & Exp)

8.90 mm

20.90 mm

88.00 mm

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Strip

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Special Warning for Female Patients



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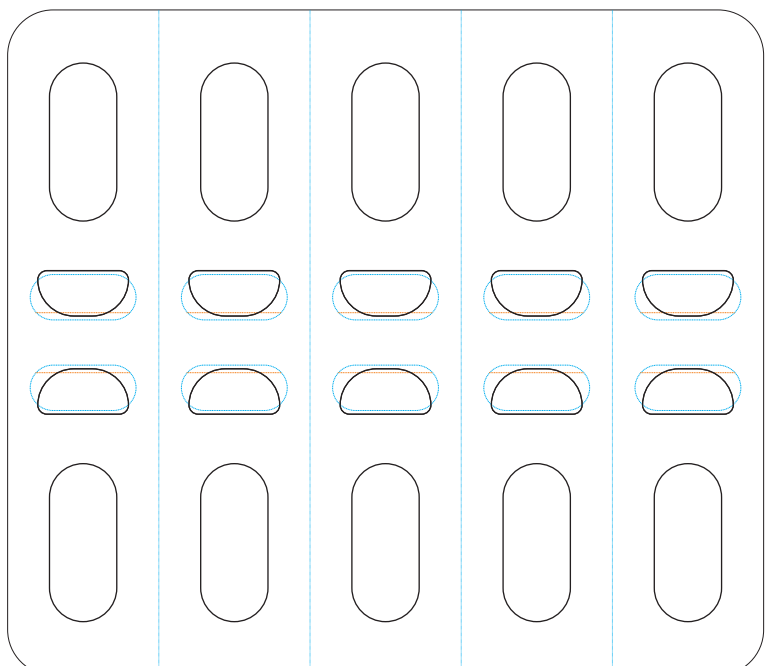
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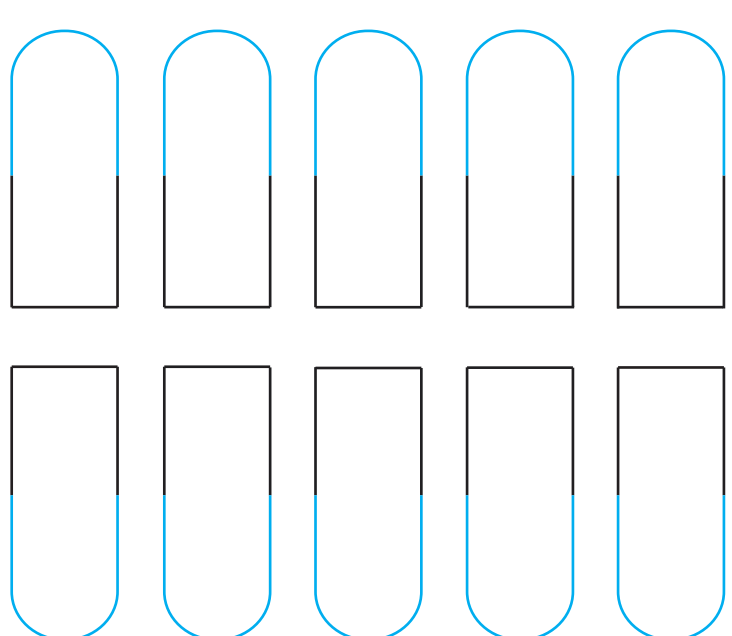
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Non Varnish Area

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Attention: Absorica and Absorica LD are NOT substitutable given that the bioavailability and dosage of these products are different (Prescription Pack)

24 mg isotretinoin, USP

Each capsule contains 10 Capsules

Absorica LD™ (isotretinoin) Capsules, USP

24 mg

Rx only

NDC 10631-005-69

Dispense with enclosed Medication Guide.

FEMALE PATIENTS: DO NOT GET PREGNANT

Absorica LD Causes Serious Birth Defects

Highlights of Warning to Female Patients.
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Manufactured by:
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New Brunswick, NJ 08901

Distributed by:
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Cranbury, NJ 08512

SEAL TAB closure

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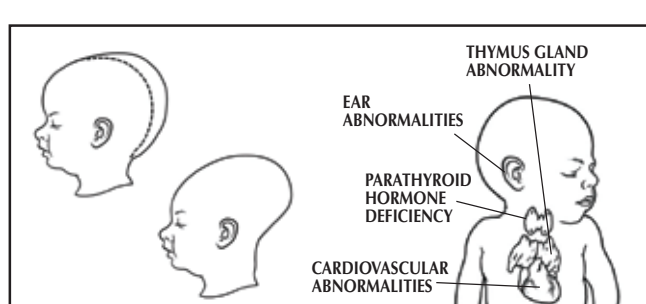
October 2021

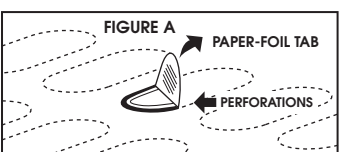
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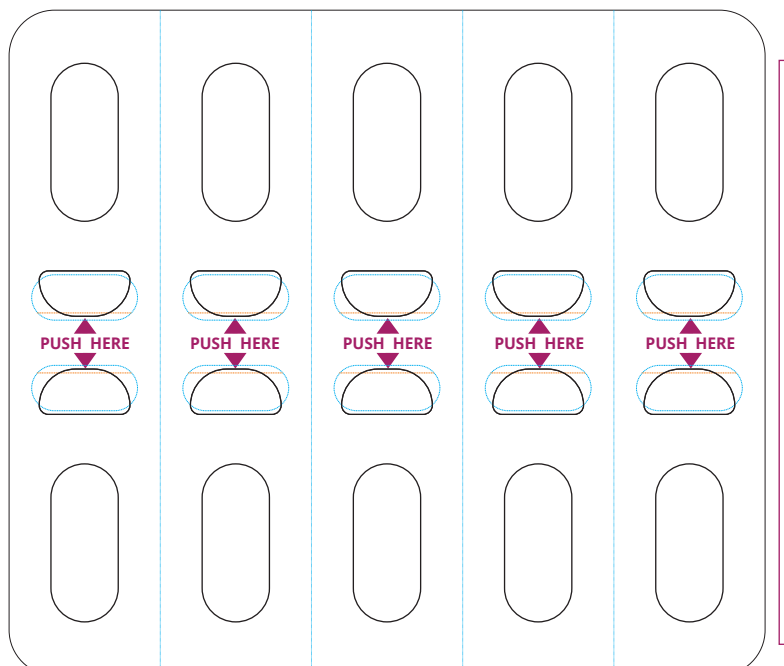




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WARNING TO FEMALE PATIENTS: DO NOT GET PREGNANT

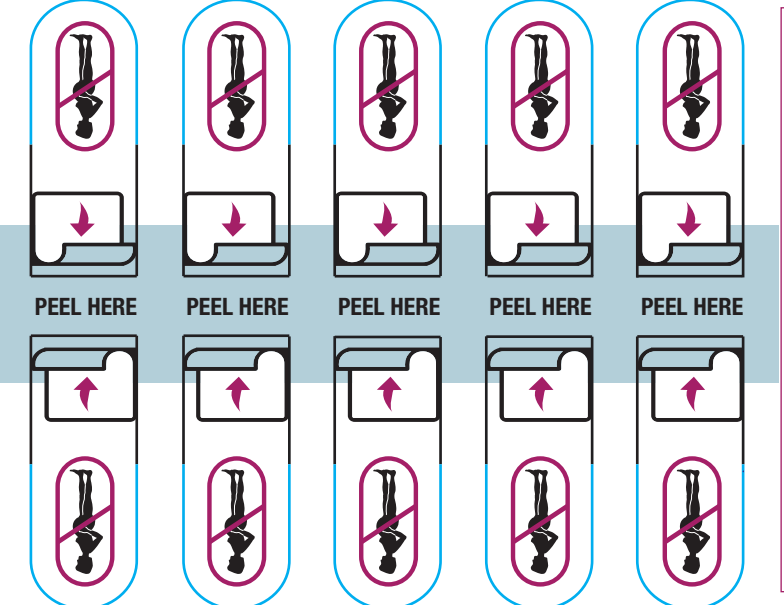


1
DIRECTIONS FOR REMOVING EACH CAPSULE:
An arrow on the reverse side of the blister pack points to step 2 on reverse side.


OR YOU MAY NOT TAKE ABSORICA LD IF YOU ARE PREGNANT.

YOU MUST NOT TAKE ABSORICA LD IF YOU ARE PREGNANT OR MAY BECOME PREGNANT DURING TREATMENT.





2
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(for Lot & Exp)

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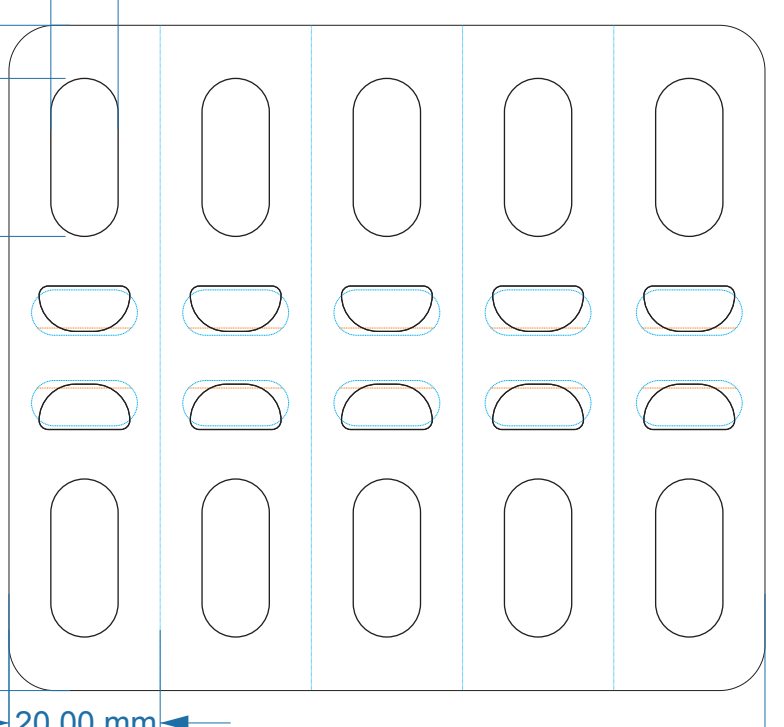
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Most people have further questions after reading so much important information about pregnancy prevention and birth defects. If there is anything you are not sure about, do **not** take Absorica LD until your questions have been answered by your doctor.

Mental problems and suicide

Some patients have become depressed or developed other serious mental problems while they were taking isotretinoin or shortly after stopping isotretinoin. Some patients taking isotretinoin have had thoughts of ending their own lives (suicidal thoughts). Some people have tried to end their own lives (attempted suicide) and some people have ended their own lives (committed suicide). There have been reports of patients on isotretinoin becoming aggressive or violent.

Stop taking Absorica LD and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells.
- Lose interest in activities you once enjoyed.
- Sleep too much or have trouble sleeping.
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence).
- Have a change in your appetite or body weight.
- Have trouble concentrating.
- Withdraw from your friends or family.
- Feel like you have no energy.
- Have feelings of worthlessness or guilt.
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts).
- Start acting on dangerous impulses.
- Start seeing or hearing things that are not real.

Tell your doctor if you or someone in your family has ever had a mental illness or if you take any medicines for a mental illness (for example, depression).

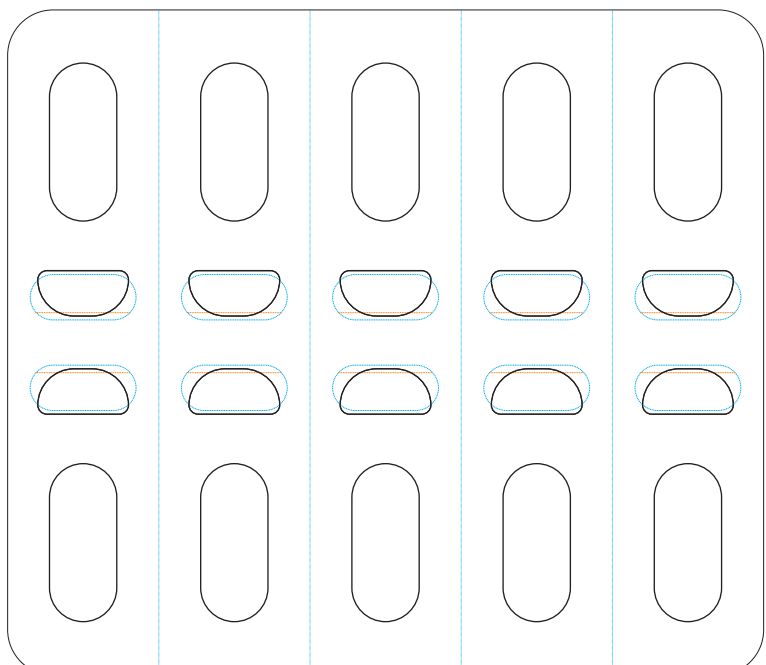
Other serious side effects to watch for

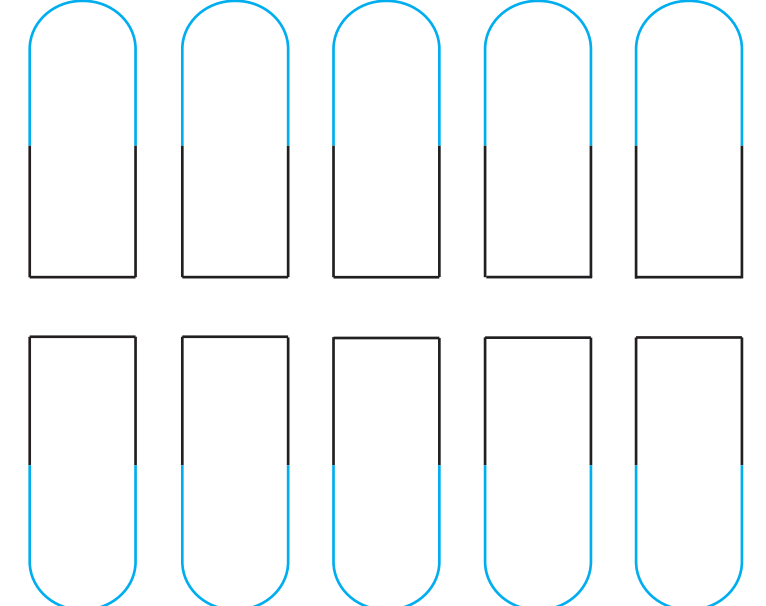
Stop taking Absorica LD and call your doctor if you develop any of the problems on this list or any other unusual or severe problems. If not treated, they could lead to serious health problems. Serious permanent problems do not happen often.

- Headaches, nausea, vomiting, blurred vision (increased brain pressure).
- Severe stomach pain, diarrhea, rectal bleeding, or trouble swallowing.
- Yellowing of your skin or eyes and/or dark urine.
- Changes in hearing.
- Allergic reactions (if you know you are sensitive to "parabens", tell your doctor because it is a preservative in the gelatin capsule of Absorica LD).
- Bone or muscle pain.
- Vision changes, including trouble seeing at night (this can start suddenly, so be very careful when driving or operating any vehicle at night).
- Persistent fever, chills, or sore throat.

Other Important Information is found in the Medication Guide and in the booklets from your doctor:

- Common side effects that are not serious but that you should tell your doctor about.
- How to take Absorica LD.
- Things to avoid during Absorica LD treatment.
- Ways to get more information if you need it.





SAP CODE : 0000000

Card Open Size : 617 x 130 mm
Card Close Size : 118 x 13 x 130 mm
Track : A25/10/2021

PHARMACISTS: DISPENSE INTACT
PLACE PRESCRIPTION LABEL HERE

PATIENT: READ INFORMATION CAREFULLY

Attention: Absorica and Absorica LD are NOT substitutable given that the bioavailability and dosage of these products are different.

28 mg
Absorica LD™
(isotretinoin) Capsules, USP
Each capsule contains 28 mg isotretinoin, USP (Prescription Pack)

Dispense with enclosed Medication Guide.
Attention Pharmacist: NDC 10631-006-69 Rx only

FEMALE PATIENTS: DO NOT GET PREGNANT

Absorica LD Causes Serious Birth Defects
Highlights of Warning to Female Patients.
(It is important to watch the video and read all information in the materials given to you by your doctor.)

- You MUST NOT take Absorica LD if you are pregnant because any amount can cause severe birth defects, even if taken for short periods during pregnancy.
- You MUST NOT become pregnant 1 month before, during, and for 1 month after you stop taking Absorica LD.
- You will not get your first prescription for Absorica LD until there is proof you have had 2 negative pregnancy tests as instructed by your doctor (a negative test means that it does not show pregnancy) and you have interacted with the iPLEDGE system to answer questions about program requirements.
- You cannot get monthly refills for Absorica LD unless there is proof that you have had a negative pregnancy test conducted in a lab every month during Absorica LD treatment.
- Even the best methods of birth control can fail. Therefore, 2 separate, effective forms of birth control must be used at the same time for at least 1 month before, during, and for 1 month after you stop taking Absorica LD.
- Stop taking Absorica LD right away and call your doctor immediately if you have sex without birth control, miss your period or think you are pregnant while you are taking Absorica LD. If you think you are pregnant in the month after you have stopped Absorica LD treatment, call your doctor immediately.

Manufactured by: **Ohm Laboratories Inc.**, New Brunswick, NJ 08901
Distributed by: **SUN Pharmaceutical Industries, Inc.**, Cranbury, NJ 08512

SEAL TAB CLOSURE
Non Varnish Area

October 2021

FEMALE PATIENTS: DO NOT GET PREGNANT

Very severe birth defects have occurred with isotretinoin use including:

- Severe Internal Defects:** defects that you cannot see—involving the brain (including lower IQ scores), heart, glands and nervous system.
- Severe External Defects:** defects that you can see—such as low-set, deformed or absent ears, wide-set eyes, depressed bridge of nose, enlarged head and small chin.

FIGURE A: PAPER-FOIL TAB TO REMOVE. PERFORATIONS.

This package is child-resistant. **Keep out of reach of children.**
STORE AT 20° C - 25° C (68° F - 77° F), EXCURSION PERMITTED BETWEEN 15° C - 30° C (59° F - 86° F) [SEE USP CONTROLLED ROOM TEMPERATURE.]
PROTECT FROM LIGHT.

WARNING TO FEMALE PATIENTS ABSORICA LD CAUSES SEVERE BIRTH DEFECTS.

OR YOU MAY BECOME PREGNANT DURING TREATMENT.

YOU MUST NOT TAKE ABSORICA LD IF YOU ARE PREGNANT OR MAY BECOME PREGNANT DURING TREATMENT.

1 DIRECTIONS FOR REMOVING EACH CAPSULE: An orange seal tab is present on each side.

2 Peel the top of the board along the perforations to lift each capsule. Do not touch the seal tab.

3 Keep package intact so that it will continue to provide the important information you should know as you take Absorica LD.

Non Varnish Area (for Lot & Exp)

Strip

0.70 mm
23.90 mm
88.00 mm
20.00 mm
100.00 mm

IMPORTANT INFORMATION FOR ALL PATIENTS:
It is important for your health that you read all the information you received with this prescription and from your doctor.

This package provides reminders of important safety facts about Absorica LD, but it does not contain all the information you need to know. It is important for you to know how to take Absorica LD correctly and what side effects to watch for.

Read all the information you get about Absorica LD from your doctor and pharmacist, including the **Medication Guide** provided with this package.

You should read, understand and sign a Patient Information/Informed Consent form before you take Absorica LD. Contact your doctor if you have not signed this form (male patients and female patients who cannot get pregnant must sign 1 form and female patients who can get pregnant must sign 2 forms).

Never share Absorica LD because it can cause serious side effects including **severe birth defects**.

Before you start taking Absorica LD, tell your doctor if you:

- Are currently taking an oral or injected corticosteroid or an anticonvulsant (seizure) medication.
- Take part in sports where you are more likely to break a bone.
- Have mental problems, anorexia nervosa (a type of eating disorder), back pain, a history of problems with healing of bone fractures, or problems with bone metabolism.



Special Warning for Female Patients

Absorica LD causes serious birth defects. Do NOT take Absorica LD if you are pregnant.

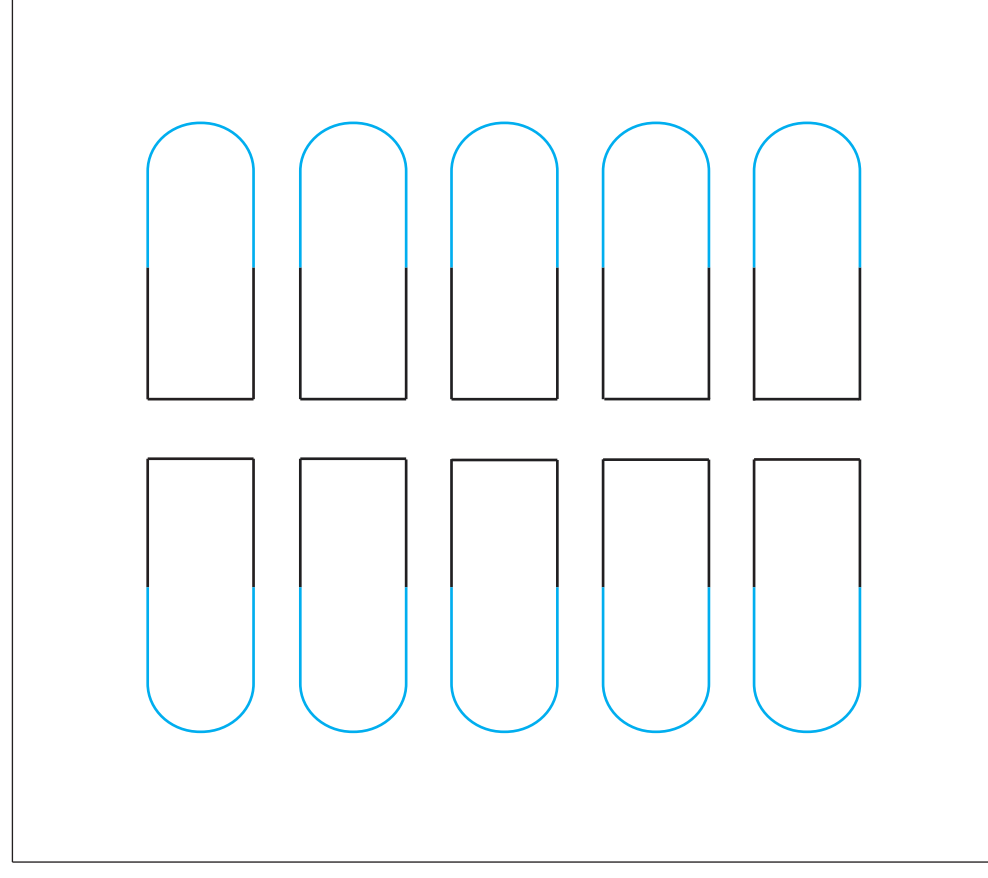
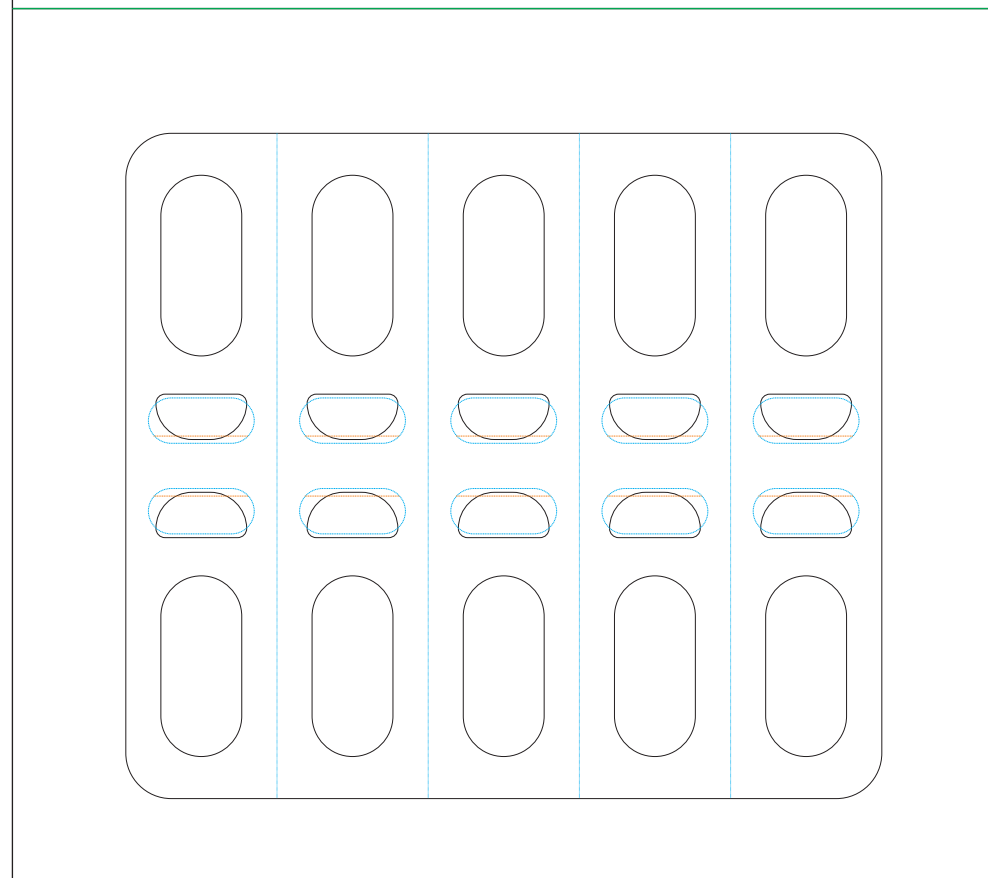
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Mental problems and suicide
Some patients have become depressed or developed other serious mental problems while they were taking isotretinoin or shortly after stopping isotretinoin. Some patients taking isotretinoin have had thoughts of ending their own lives (suicidal thoughts). Some people have tried to end their own lives (attempted suicide) and some people have ended their own lives (committed suicide). There have been reports of patients on isotretinoin becoming aggressive or violent.

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 - Sleep too much or have trouble sleeping.
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 - Withdraw from your friends or family.
 - Feel like you have no energy.
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SAP CODE : 000000



Card Open Size : 617 x 130 mm
Card Close Size : 118 x 13 x 130 mm

Track : A25/10/2021

120.00 mm

13.00 mm

120.00 mm


14.00 mm

118.00 mm

2.00 mm

118.00 mm

115.00 mm



Non Varnish Area

PHARMACISTS: PLACE PRESCRIPTION LABEL HERE

Absorica LD™
(isotretinoin) Capsules, USP
32 mg
10 Capsules (Prescription Pack)

Attention: Absorica and Absorica LD are NOT substitutable given that the bioavailability and dosage of these products are different.

Attention Pharmacist: Dispense with enclosed Medication Guide.

NDC 10631-007-69
Rx only

Non Varnish Area

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Manufactured by:
Olm Laboratories Inc.
New Brunswick, NJ 08901

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

Seal Tab Closure
Non Varnish Area

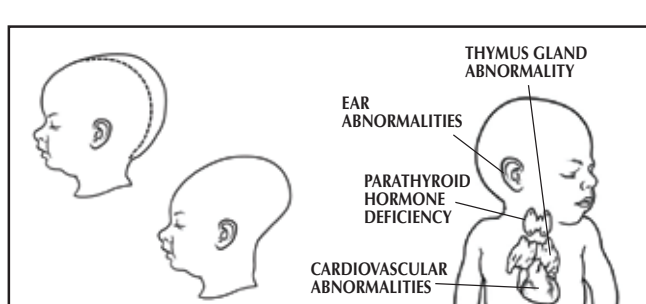
October 2021

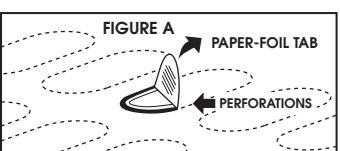


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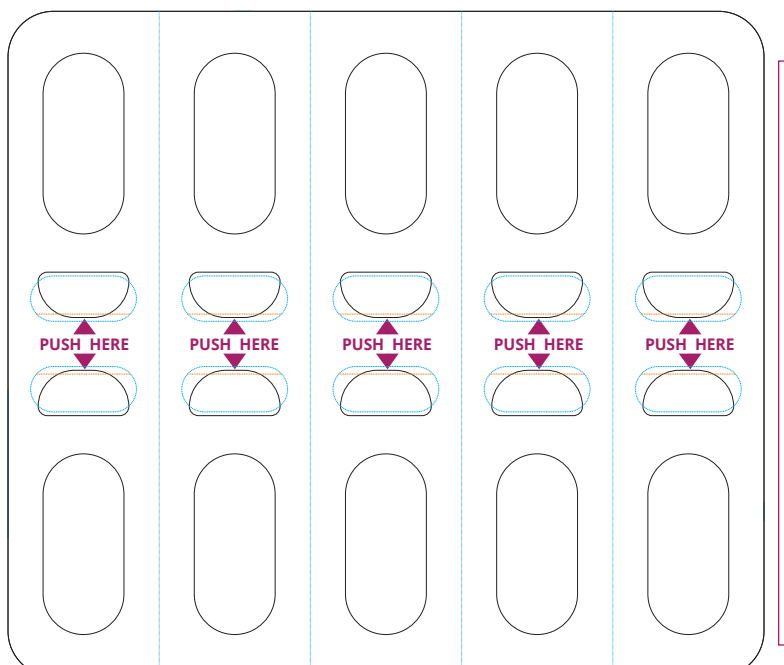




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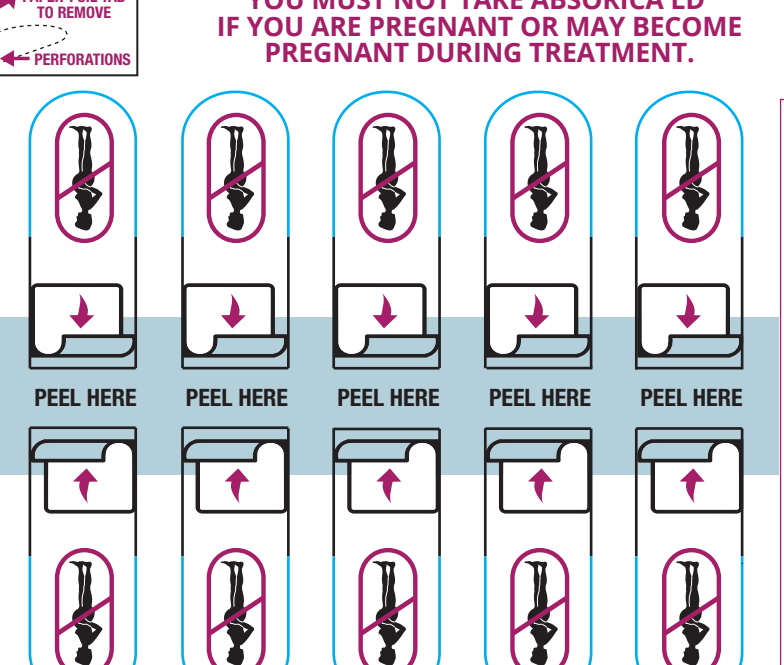


1
DIRECTIONS FOR REMOVING EACH CAPSULE
An electronic arrow will appear to help you remove a PULL TAB


YOU MUST NOT TAKE ABSORICA LD IF YOU ARE PREGNANT OR MAY BECOME PREGNANT DURING TREATMENT.

2
Grasp the top of the blister pack and carefully peel along the perforation to free the cap. See Figure 1 on reverse side.

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3
Keep package intact so that it will continue to provide the important information you should know as you take Absorica LD.



Non Varnish Area
(for Lot & Exp)

130.00 mm

7.70 mm

23.90 mm

88.00 mm

20.00 mm

100.00 mm

Strip



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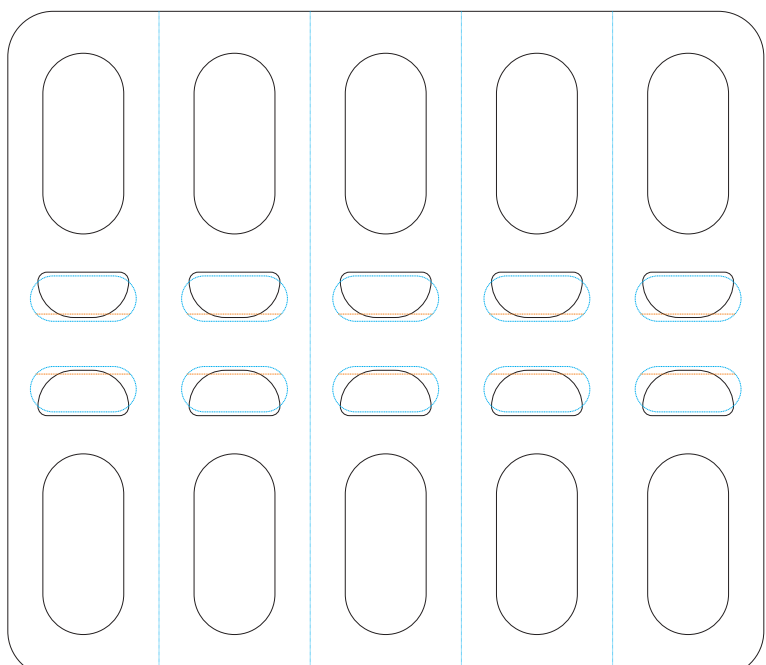
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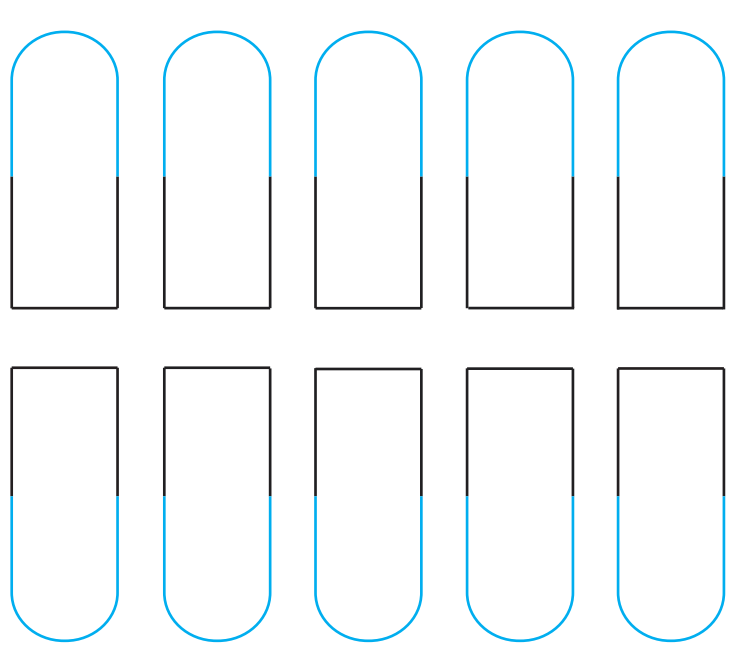
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SAP CODE : 000000



Card Open Size : 617 x 130 mm
Card Close Size : 118 x 13 x 130 mm
Track : A25/10/2021



David
Lewis

Digitally signed by David Lewis

Date: 4/07/2022 12:32:27PM

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