

Non Varnish Area

Each capsule contains
10 mg Isotretinoin, USP
30 Capsules
(3 x 10 Prescription Packs)

Absorica®
(isotretinoin) Capsules
NDC 10631-115-31
Attention Pharmacist:
Dispense with enclosed
Medication Guide.

PROTECT
FROM LIGHT



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CONTRAINDICATED IN PREGNANCY

PHARMACIST: DISPENSE PRESCRIPTION PACKS INTACT.

DOSAGE: See Prescribing Information.

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.

Reminders for Pharmacists:

- Dispense isotretinoin only for registered patients after obtaining authorization from the iPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
- Write Risk Management Authorization number on the prescription
- Dispense no more than a 30-day supply. No refills.
- Dispense Prescription Packs intact
- Do not dispense after the "Do not dispense to Patient After" date
- A Medication Guide is included in each Prescription Pack

September 2019

Manufactured by:
Galephar Pharmaceutical
Research, Inc.
Humacao, PR 00792

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



Non Varnish Area
(for Lot & Exp)
37.721mm x 23.078mm



(b) (4)

PHARMACISTS:
DISPENSE INTACT.
PLACE PRESCRIPTION LABEL HERE



Non Varnish Area

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Rx only
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Prescription Pack
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Absorica
(isotretinoin) Capsules
10 mg

NDC 10631-115-69

Attention Pharmacist:
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FEMALE PATIENTS: DO NOT GET PREGNANT

Absorica 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 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.
- ▲ You will not get your first prescription for Absorica 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 unless there is proof that you have had a negative pregnancy test conducted in a lab every month during Absorica 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.
- ▲ Stop taking Absorica 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. If you think you are pregnant in the month after you have stopped Absorica treatment, call your doctor immediately.

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SEAL
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Non Varnish Area

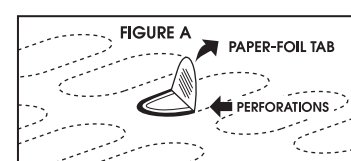
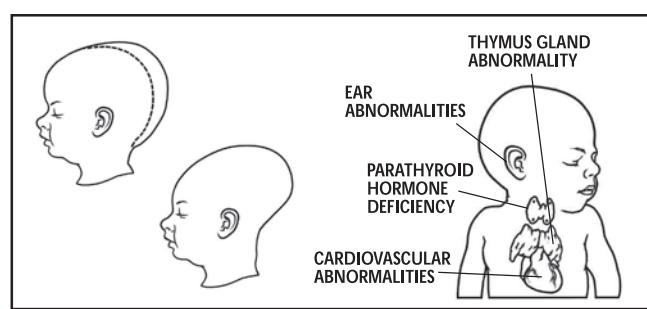
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**FEMALE PATIENTS:
DO NOT GET PREGNANT**

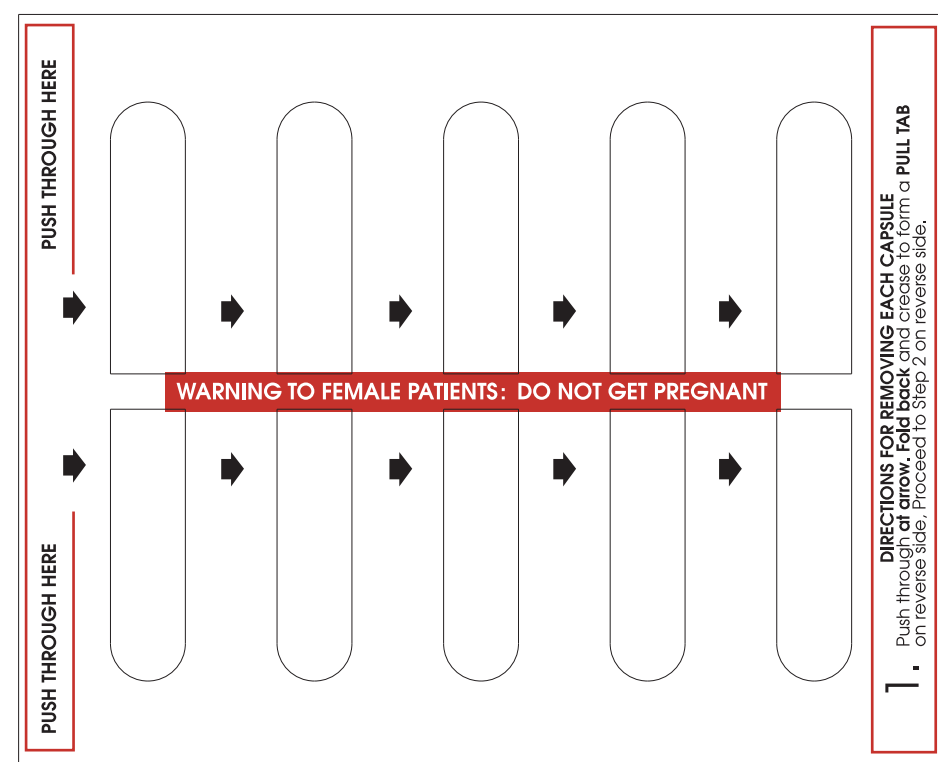
Very severe birth defects have occurred with isotretinoin use including:

- ▲ **Severe Internal Defects:** defects that you cannot see—involving the brain (including lower IQ scores), heart, glands and nervous system.
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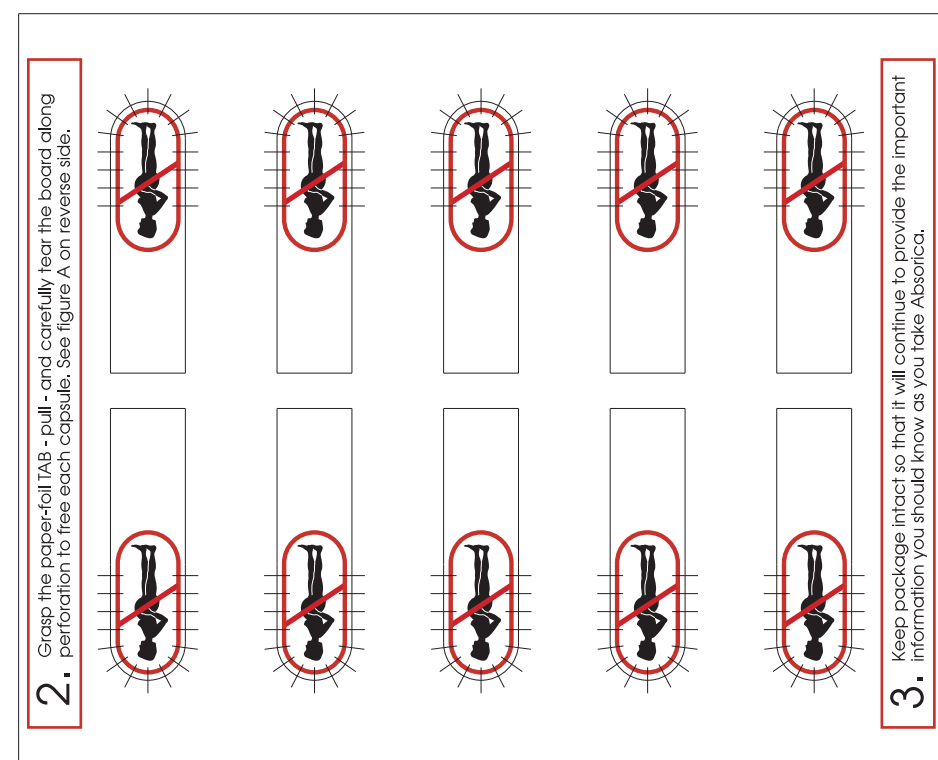
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**WARNING TO FEMALE PATIENTS
ABSORICA CAUSES SEVERE BIRTH DEFECTS.**



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

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Read all the information you get about Absorica 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. 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 because it can cause serious side effects including **severe birth defects**.

Before you start taking Absorica, 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

CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT

Absorica causes serious birth defects. Do NOT take Absorica 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. 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 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 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).

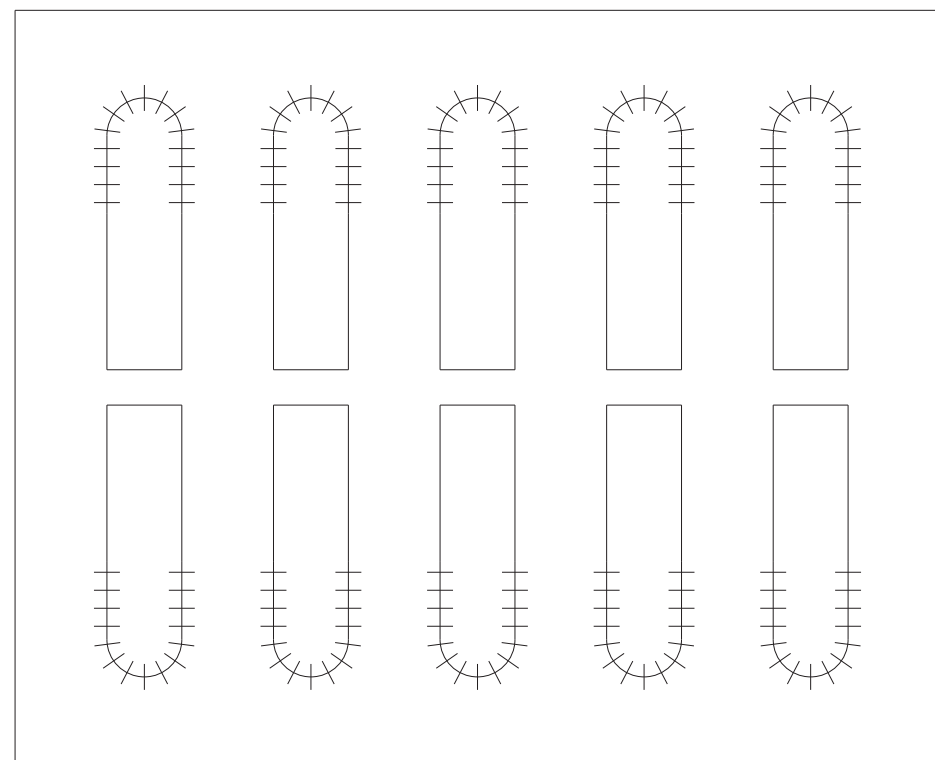
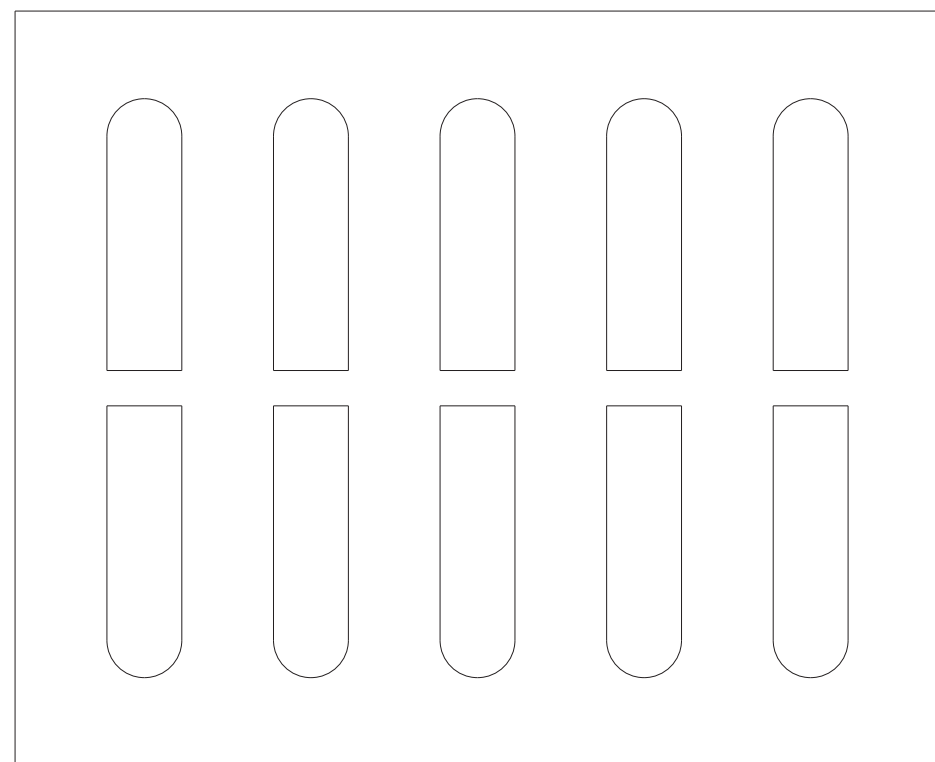
Other serious side effects to watch for

Stop taking Absorica 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).
- 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.
- Things to avoid during Absorica treatment.
- Ways to get more information if you need it.



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Reminders for Pharmacists:

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CAUSES BIRTH DEFECTS



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N 31 10631 11631 16



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Absorica 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 if you are pregnant because any amount can cause severe birth defects, even if taken for short periods during pregnancy.
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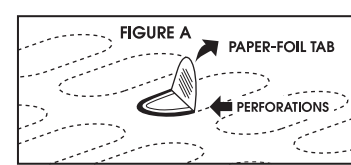
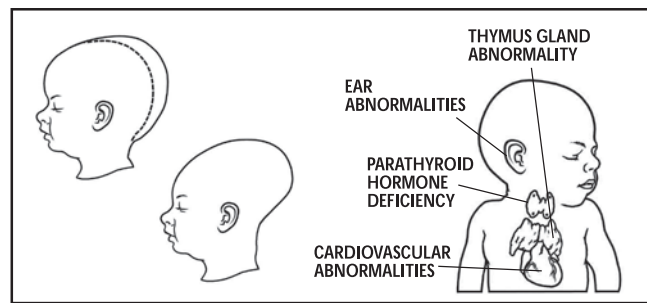
September 2019



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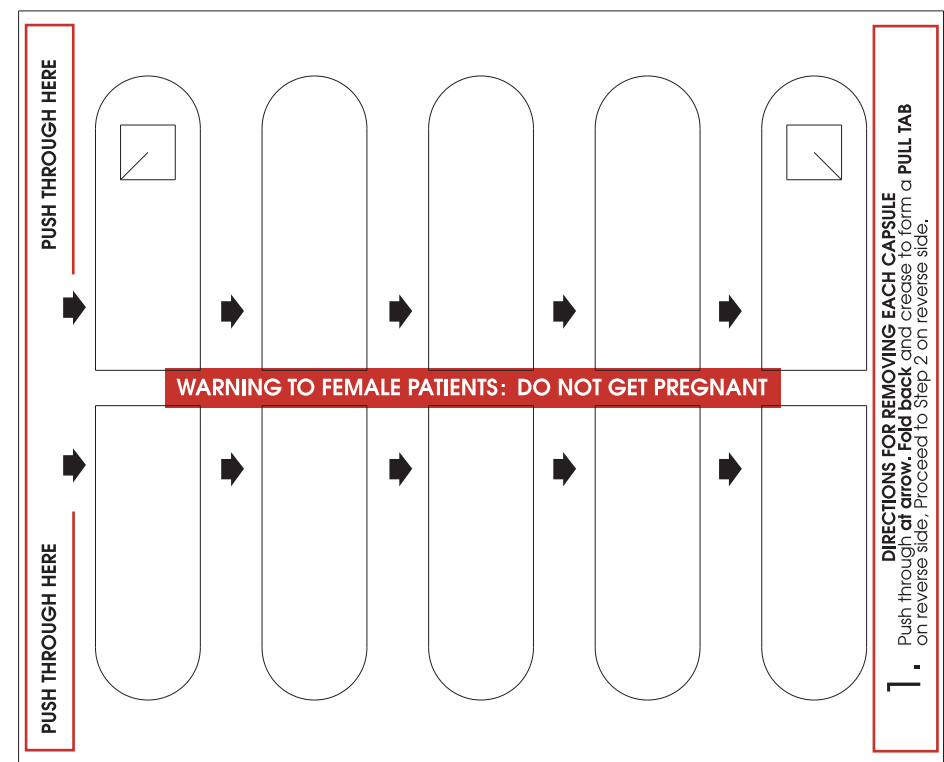
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WARNING TO FEMALE PATIENTS ABSORICA CAUSES SEVERE BIRTH DEFECTS.



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GK-246



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Special Warning for Female Patients

CAUSES BIRTH DEFECTS



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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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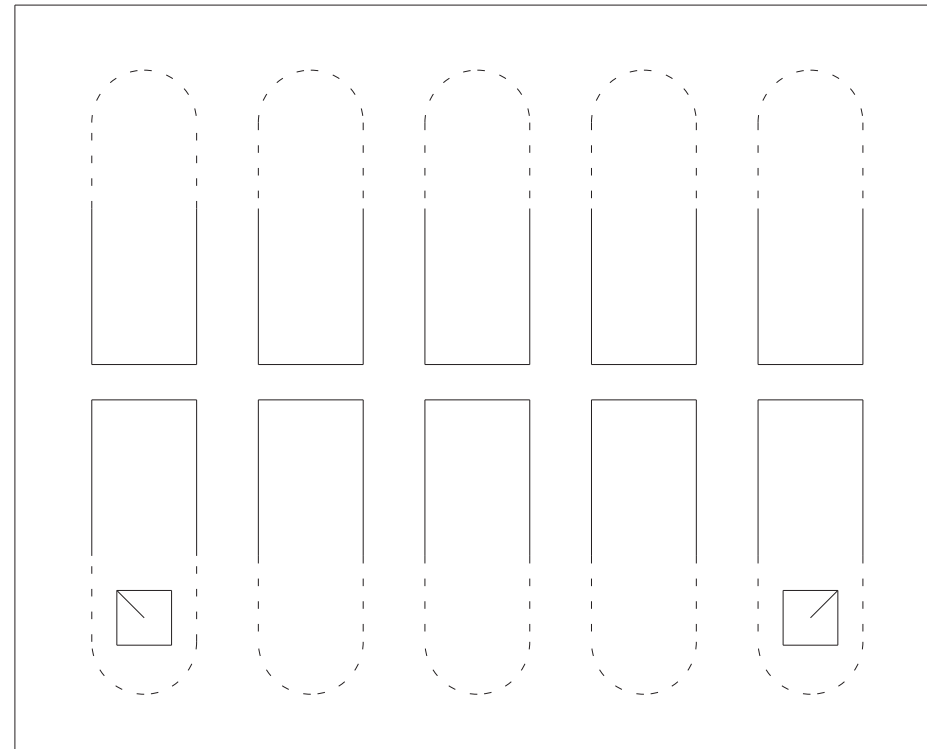
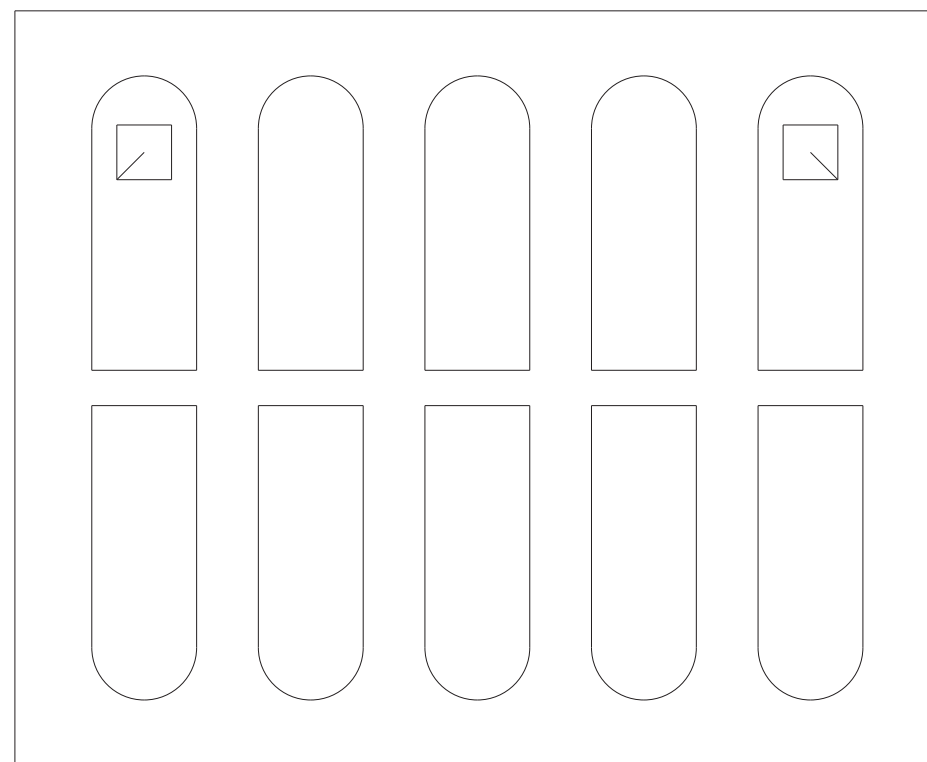
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NDC 10631-133-31
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CONTRAINDICATED IN PREGNANCY

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37.721mm x 23.078mm



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NDC 10631-133-31

Absorica®
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25 mg

Contains FD&C Yellow No. 5 (tartrazine) as a color additive.

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CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT

(b) (4)



6 511065111393 N

25 mg

Absorica®

(isotretinoin) Capsules

NDC 10631-133-69

Attention Pharmacist: Dispense with enclosed Medication Guide.

Each capsule contains 25 mg isotretinoin, USP

10 Capsules Prescription Pack

PATIENT: READ INFORMATION CAREFULLY

Rx only

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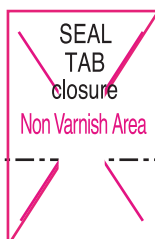
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Cranbury, NJ 08512



September 2019

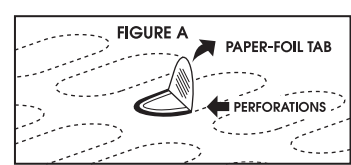
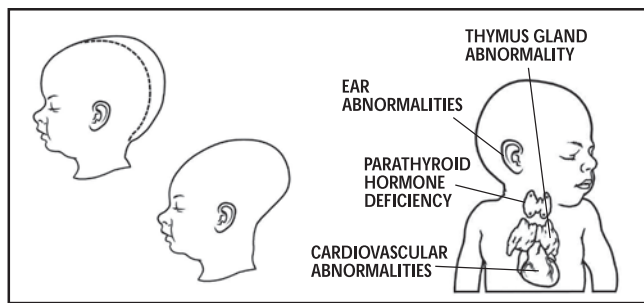


GK-333

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.



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 CAUSES SEVERE BIRTH DEFECTS.

WARNING TO FEMALE PATIENTS: DO NOT GET PREGNANT

PUSH THROUGH HERE

DIRECTIONS FOR REMOVING EACH CAPSULE
1. Push through at arrow. Fold back and crease to form a pull tab on reverse side. Proceed to step 2 on reverse side.

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

2. Grasp the paper-foil TAB - pull - and carefully tear the board along perforation to free each capsule. See Figure A on reverse side.

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



GK-333

62.434mm x 15.368mm
Non Varnish Area
(for Lot & Exp)

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, but it does not contain all the information you need to know. It is important for you to know how to take Absorica correctly and what side effects to watch for.

Read all the information you get about Absorica 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. 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 because it can cause serious side effects including **severe birth defects**.

Before you start taking Absorica, 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

CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT

Absorica causes serious birth defects. Do NOT take Absorica 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. 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 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 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).

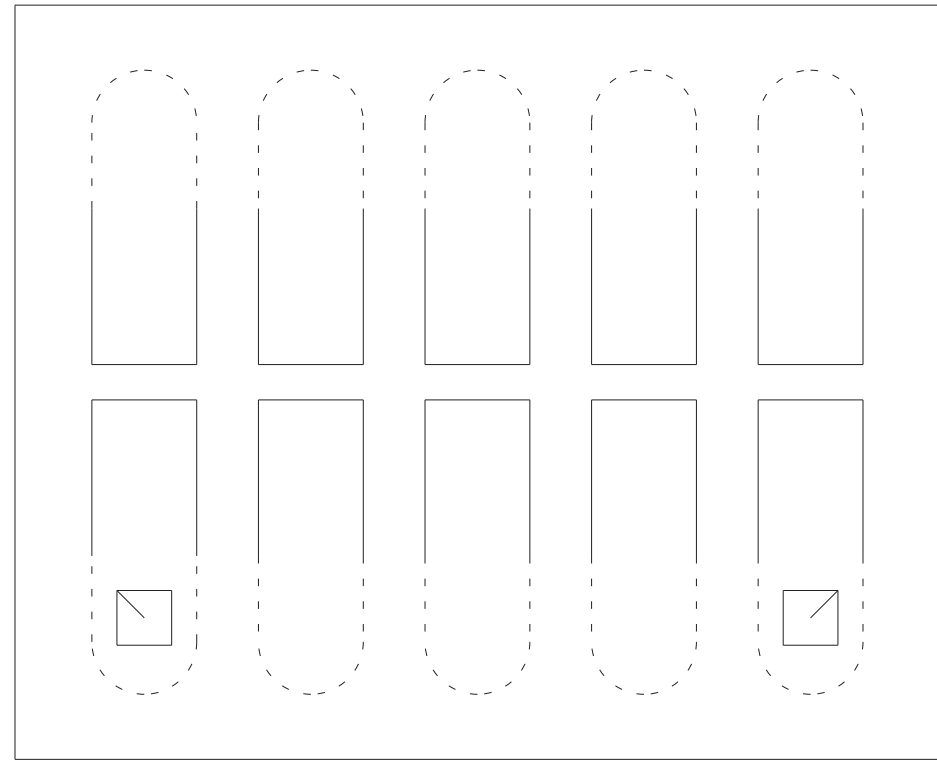
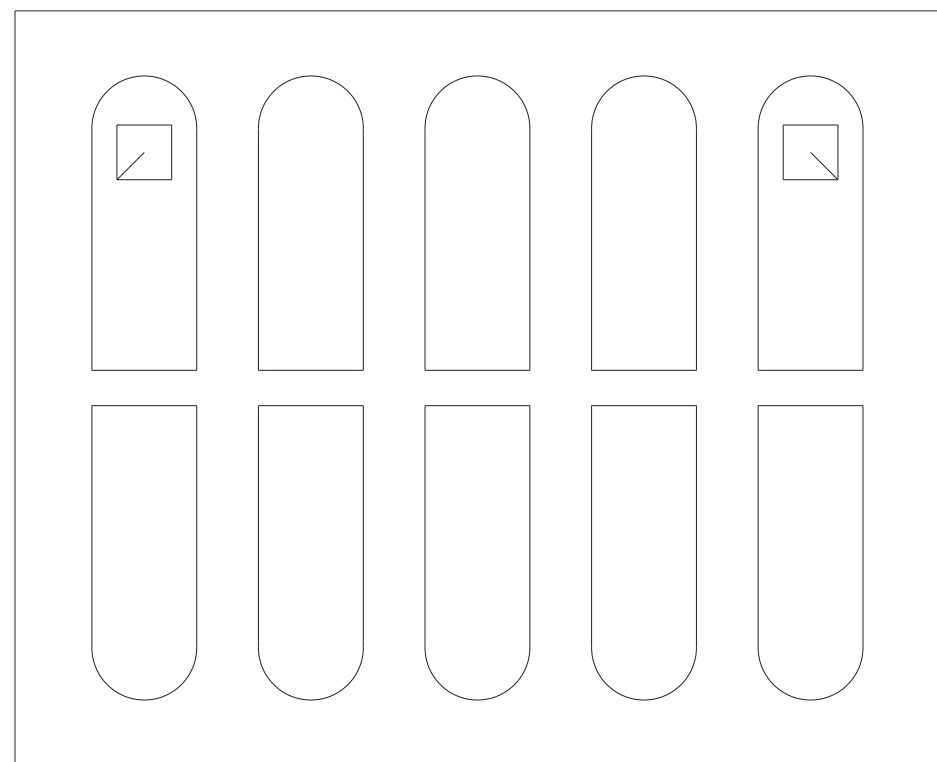
Other serious side effects to watch for

Stop taking Absorica 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).
- 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.
- Things to avoid during Absorica treatment.
- Ways to get more information if you need it.



PROTECT FROM LIGHT

Attention Pharmacist: Dispense with enclosed Medication Guide.

NDC 10631-117-31

Absorica[®]
(isotretinoin) Capsules

30 mg

Each capsule contains 30 mg Isotretinoin, USP

30 Capsules
(3 x 10 Prescription Packs)



Attention Pharmacist: Dispense with enclosed Medication Guide.

NDC 10631-117-31

Absorica[®]
(isotretinoin) Capsules

Rx only

30 mg

Each capsule contains 30 mg Isotretinoin, USP

30 Capsules
(3 x 10 Prescription Packs)

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

CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT

PROTECT FROM LIGHT

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Absorica[®]
(isotretinoin) Capsules
NDC 10631-117-31
Attention Pharmacist: Dispense with enclosed Medication Guide.



GK-251

Special Instructions to Pharmacists:
• Only fill Absorica after authorization from the iPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
• An Absorica Medication Guide is included in each Prescription Pack
• Dispense no more than a 30-day supply
• Do not remove Prescription Packs from carton until dispensed



CONTRAINDICATED IN PREGNANCY

PHARMACIST: DISPENSE PRESCRIPTION PACKS INTACT.

DOSAGE: See Prescribing Information.

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.

Reminders for Pharmacists:

- Dispense isotretinoin only for registered patients after obtaining authorization from the iPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
- Write Risk Management Authorization number on the prescription
- Dispense no more than a 30-day supply. No refills.
- Dispense Prescription Packs intact
- Do not dispense after the "Do not dispense to Patient After" date
- A Medication Guide is included in each Prescription Pack

September 2019

Manufactured by:
Galephar Pharmaceutical Research, Inc.
Humacao, PR 00792

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



CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT



N 311063111173113



GK-251

Non Varnish Area

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

Rx only

READ INFORMATION CAREFULLY

PATIENT: Prescription Pack

10 Capsules

Each capsule contains 30 mg Isotretinoin, USP

30 mg

Absorica® (isotretinoin) Capsules

NDC 10631-117-69

Attention Pharmacist: Dispense with enclosed Medication Guide.

6 0 6 3 1 1 1 7 1 2 6 9 3 N

PLACE PRESCRIPTION LABEL HERE

PHARMACISTS: DISPENSE INTACT.

FEMALE PATIENTS: DO NOT GET PREGNANT

Absorica Causes Serious Birth Defects

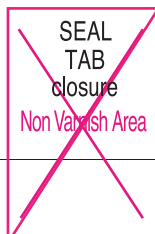
Highlights of Warning to Female Patients.

(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 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.
- ▲ You will not get your first prescription for Absorica 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 unless there is proof that you have had a negative pregnancy test conducted in a lab every month during Absorica 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.
- ▲ Stop taking Absorica 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. If you think you are pregnant in the month after you have stopped Absorica treatment, call your doctor immediately.

Manufactured by:
Galephar Pharmaceutical
Research, Inc.
Humacao, PR 00792

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



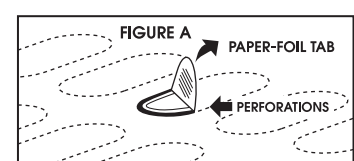
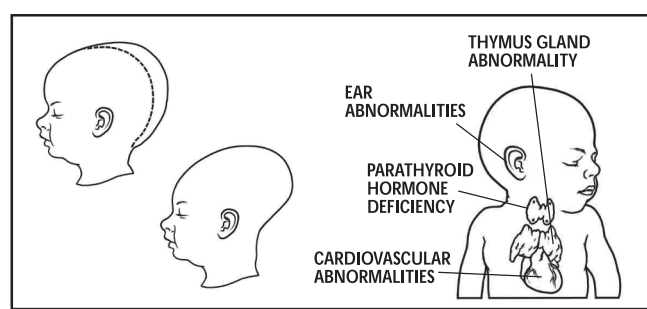
September 2019



FEMALE PATIENTS: DO NOT GET PREGNANT

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

WARNING TO FEMALE PATIENTS: DO NOT GET PREGNANT

1. DIRECTIONS FOR REMOVING EACH CAPSULE
Push through at arrow. Fold back and crease to form a pull tab on reverse side. Proceed to Step 2 on reverse side.

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

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

2. Scrape the paper-foil tab - pull - and carefully tear the board along perforation to free each capsule. See Figure A on reverse side.

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

GK-247



62.434mm x 15.368mm
Non Varnish Area
(for Lot & Exp)

IMPORTANT INFORMATION FOR ALL PATIENTS:

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

Before you start taking Absorica, 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

CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT

Absorica causes serious birth defects. Do NOT take Absorica 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. 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 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 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.
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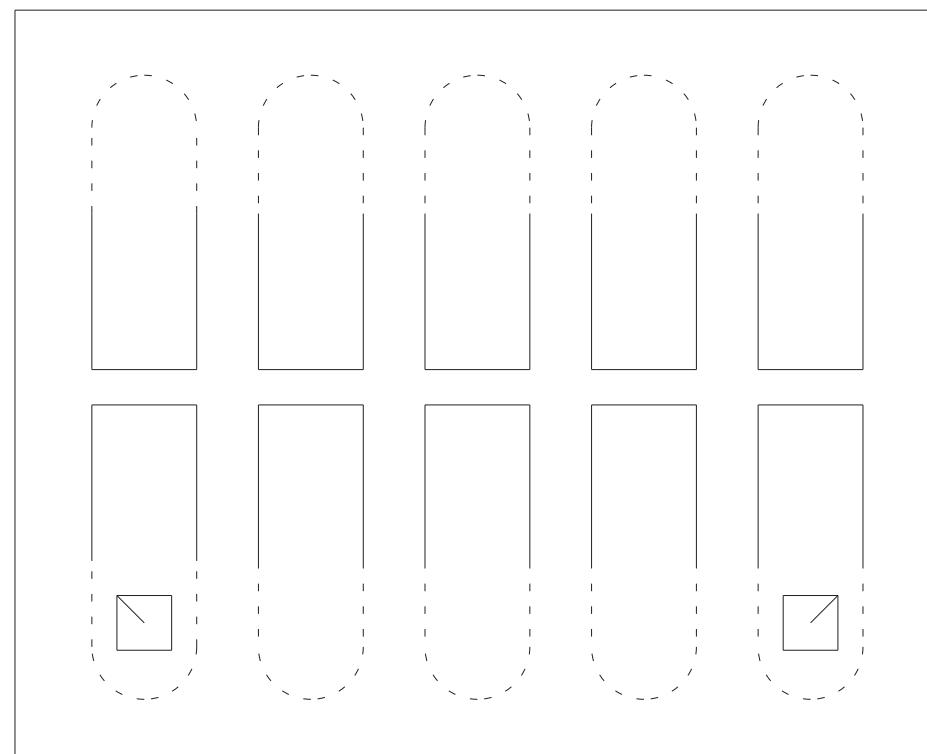
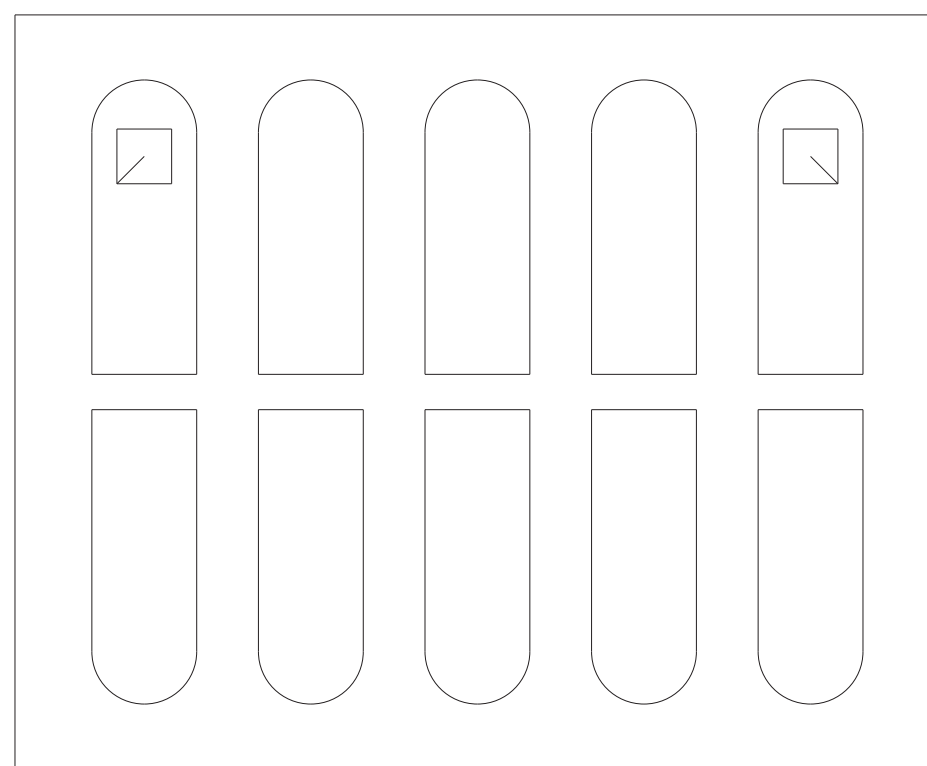
Other serious side effects to watch for

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- 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).
- 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.
- Things to avoid during Absorica treatment.
- Ways to get more information if you need it.



Non Varnish Area

Each capsule contains
35 mg Isotretinoin, USP
30 Capsules
(3 x 10 Prescription Packs)

Absorica[®]
(isotretinoin) Capsules
NDC 10631-134-31
Attention Pharmacist:
Dispense with enclosed
Medication Guide.

PROTECT
FROM LIGHT



PROTECT
FROM LIGHT

Non Varnish Area

Attention Pharmacist:
Dispense with enclosed
Medication Guide.

NDC 10631-134-31

Absorica[®]
(isotretinoin) Capsules

35 mg

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35 mg Isotretinoin, USP

30 Capsules
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Rx only

35 mg

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Special Instructions to Pharmacists:
• Only fill Absorica after authorization from the iPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
• An Absorica Medication Guide is included in each Prescription Pack
• Dispense no more than a 30-day supply
• Do not remove Prescription Packs from carton until dispensed
• Dispense Prescription Packs intact
• Do not get pregnant
CAUSES BIRTH DEFECTS

CONTRAINDICATED IN PREGNANCY

PHARMACIST: DISPENSE PRESCRIPTION PACKS INTACT.

DOSAGE: See Prescribing Information.

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.

Reminders for Pharmacists:

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- Write Risk Management Authorization number on the prescription
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- Dispense Prescription Packs intact
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September 2019

Manufactured by:
Galephar Pharmaceutical
Research, Inc.
Humacao, PR 00792

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



Non Varnish Area
(for Lot & Exp)
37.721mm x 23.078mm



(b) (4)



3 10631135693 N

35 mg

Absorica®

(isotretinoin) Capsules

NDC 10631-134-69

Attention Pharmacist:
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Medication Guide.

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10 Capsules
Prescription Pack

PATIENT:
READ INFORMATION CAREFULLY

Rx only

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bioavailability and dosage of these
products are different.

PHARMACISTS:
DISPENSE INTACT.
PLACE PRESCRIPTION LABEL HERE

SEAL
TAB
closure

Non Varnish Area

September 2019

GK-334

FEMALE PATIENTS: DO NOT GET PREGNANT

Absorica Causes Serious Birth Defects

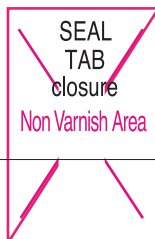
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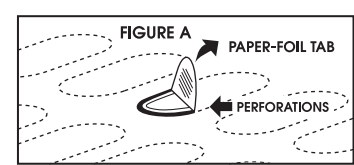
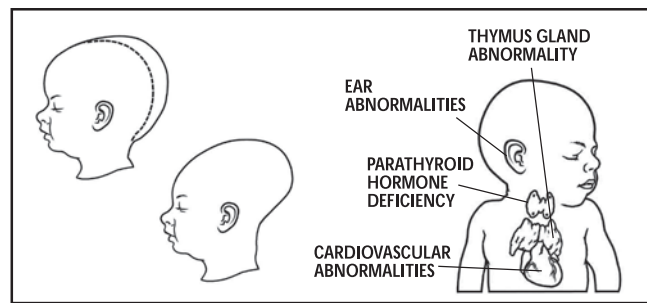
Distributed by:
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**WARNING TO FEMALE PATIENTS
ABSORICA CAUSES SEVERE BIRTH DEFECTS.**

WARNING TO FEMALE PATIENTS: DO NOT GET PREGNANT

PUSH THROUGH HERE

DIRECTIONS FOR REMOVING EACH CAPSULE
1. Push through at arrow. Fold back and crease to form a PULL TAB on reverse side. Proceed to Step 2 on reverse side.

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

2. Grasp the paper-foil TAB - pull - and carefully tear the board along perforation to free each capsule. See Figure A on reverse side.

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



62.434mm x 15.368mm
Non Varnish Area
(for Lot & Exp)

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Special Warning for Female Patients

CAUSES BIRTH DEFECTS



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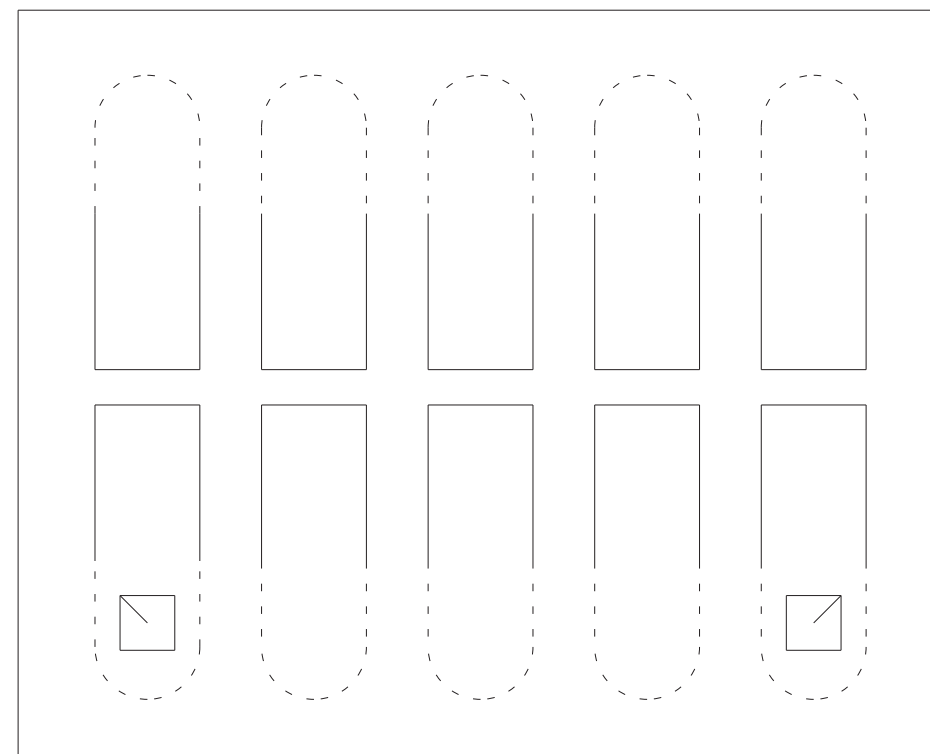
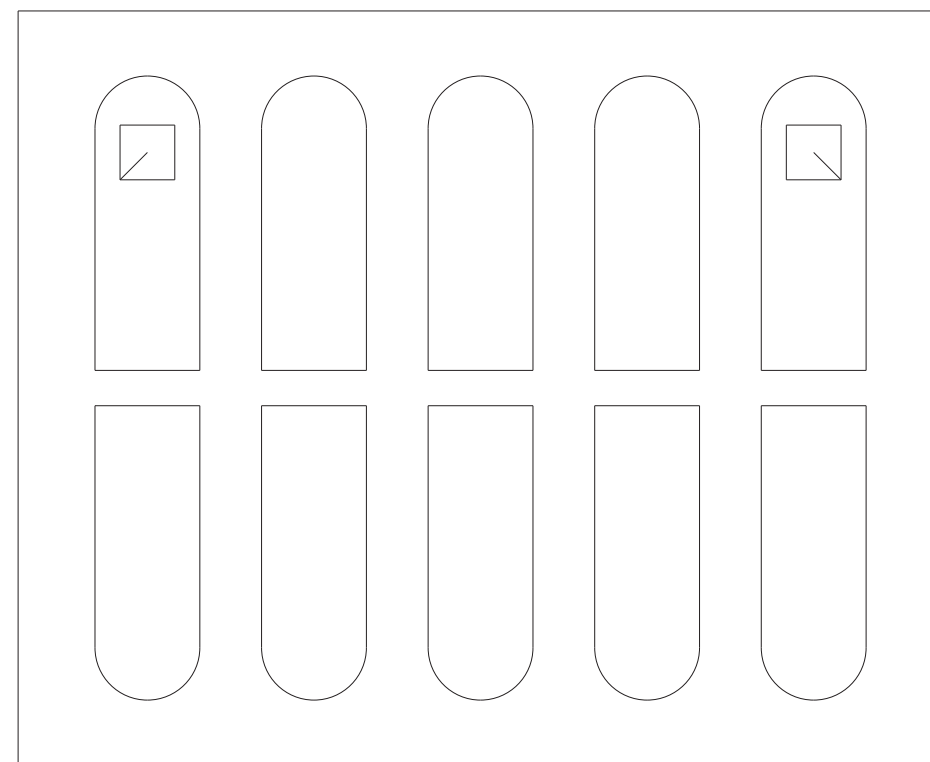
Other serious side effects to watch for

Stop taking Absorica 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).
- 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.
- Things to avoid during Absorica treatment.
- Ways to get more information if you need it.



PROTECT FROM LIGHT

Attention Pharmacist: Dispense with enclosed Medication Guide.

NDC 10631-118-31

Absorica[®]
(isotretinoin) Capsules

40 mg

Each capsule contains 40 mg Isotretinoin, USP

30 Capsules
(3 x 10 Prescription Packs)



Attention Pharmacist: Dispense with enclosed Medication Guide.

NDC 10631-118-31

Absorica[®]
(isotretinoin) Capsules

Rx only

40 mg

Each capsule contains 40 mg Isotretinoin, USP

30 Capsules
(3 x 10 Prescription Packs)

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



PROTECT FROM LIGHT



Each capsule contains 40 mg Isotretinoin, USP
30 Capsules
(3 x 10 Prescription Packs)

Absorica[®]
(isotretinoin) Capsules
NDC 10631-118-31
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(isotretinoin) Capsules

40 mg

Each capsule contains 40 mg Isotretinoin, USP

30 Capsules
(3 x 10 Prescription Packs)



Special Instructions to Pharmacists:
• Only fill Absorica after authorization from the iPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
• An Absorica Medication Guide is included in each Prescription Pack
• Dispense no more than a 30-day supply
• Do not remove Prescription Packs from carton until dispensed
• Dispense Prescription Packs intact
• Do not get pregnant
CAUSES BIRTH DEFECTS

CONTRAINDICATED IN PREGNANCY

PHARMACIST: DISPENSE PRESCRIPTION PACKS INTACT.

DOSAGE: See Prescribing Information.

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.

Reminders for Pharmacists:

- Dispense isotretinoin only for registered patients after obtaining authorization from the iPLEDGE program by calling 1-866-495-0654 or visiting www.ipledgeprogram.com
- Write Risk Management Authorization number on the prescription
- Dispense no more than a 30-day supply. No refills.
- Dispense Prescription Packs intact
- Do not dispense after the "Do not dispense to Patient After" date
- A Medication Guide is included in each Prescription Pack

September 2019

Manufactured by:
Galephar Pharmaceutical Research, Inc.
Humacao, PR 00792

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





3 10631118693 N

40 mg
(isotretinoin) Capsules

Absorica[®]

NDC 10631-118-69

Attention Pharmacist:
Dispense with enclosed
Medication Guide.

Each capsule contains
40 mg isotretinoin, USP

10 Capsules
Prescription Pack

PATIENT:
READ INFORMATION CAREFULLY

Rx only

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

PHARMACISTS:
DISPENSE INTACT.
PLACE PRESCRIPTION LABEL HERE

Non Varnish Area

FEMALE PATIENTS: DO NOT GET PREGNANT

Absorica Causes Serious Birth Defects

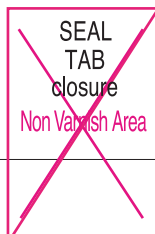
Highlights of Warning to Female Patients.

(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 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.
- ▲ You will not get your first prescription for Absorica 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 unless there is proof that you have had a negative pregnancy test conducted in a lab every month during Absorica 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.
- ▲ Stop taking Absorica 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. If you think you are pregnant in the month after you have stopped Absorica treatment, call your doctor immediately.

Manufactured by:
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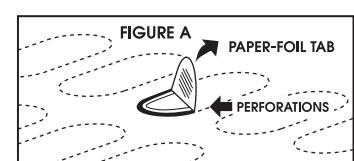
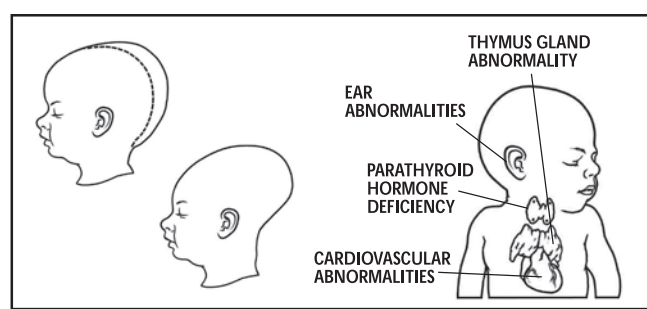


GK-248

**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.



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 CAUSES SEVERE BIRTH DEFECTS.**

WARNING TO FEMALE PATIENTS: DO NOT GET PREGNANT

PUSH THROUGH HERE

PUSH THROUGH HERE

1. DIRECTIONS FOR REMOVING EACH CAPSULE
Push through at arrow. Fold back and crease to form a pull tab on reverse side. Proceed to Step 2 on reverse side.

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

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

2. Grasp the paper-foil TAB - pull - and carefully tear the board along perforation to free each capsule. See Figure A on reverse side.

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



GK-248



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, but it does not contain all the information you need to know. It is important for you to know how to take Absorica correctly and what side effects to watch for.

Read all the information you get about Absorica 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. 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 because it can cause serious side effects including **severe birth defects**.

Before you start taking Absorica, 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

CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT

Absorica causes serious birth defects. Do NOT take Absorica 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. 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 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 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).

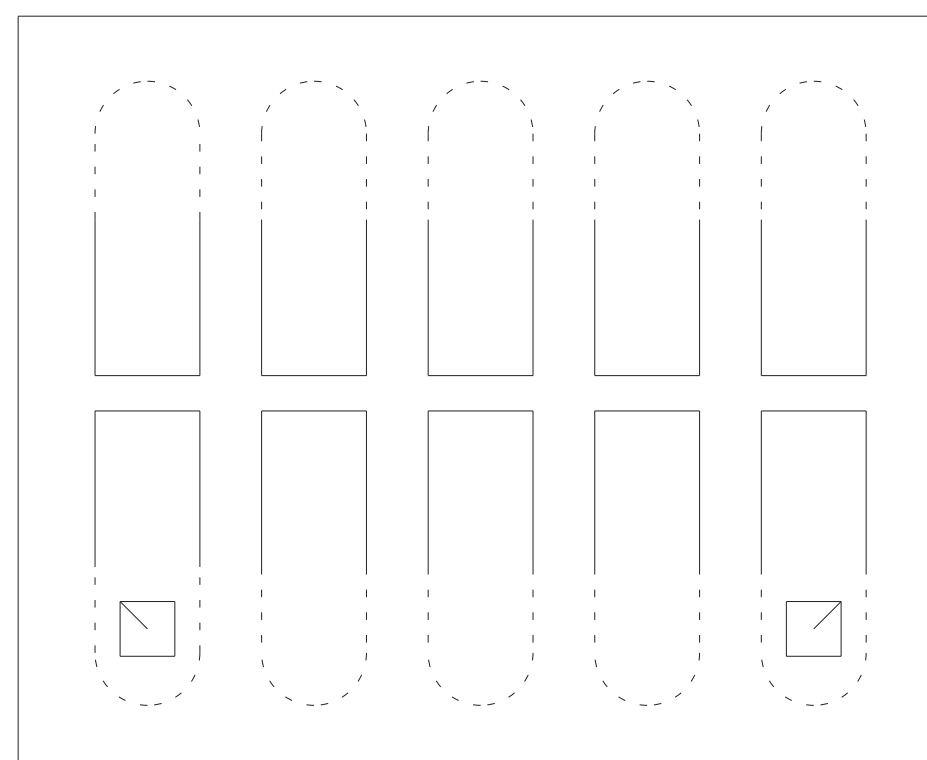
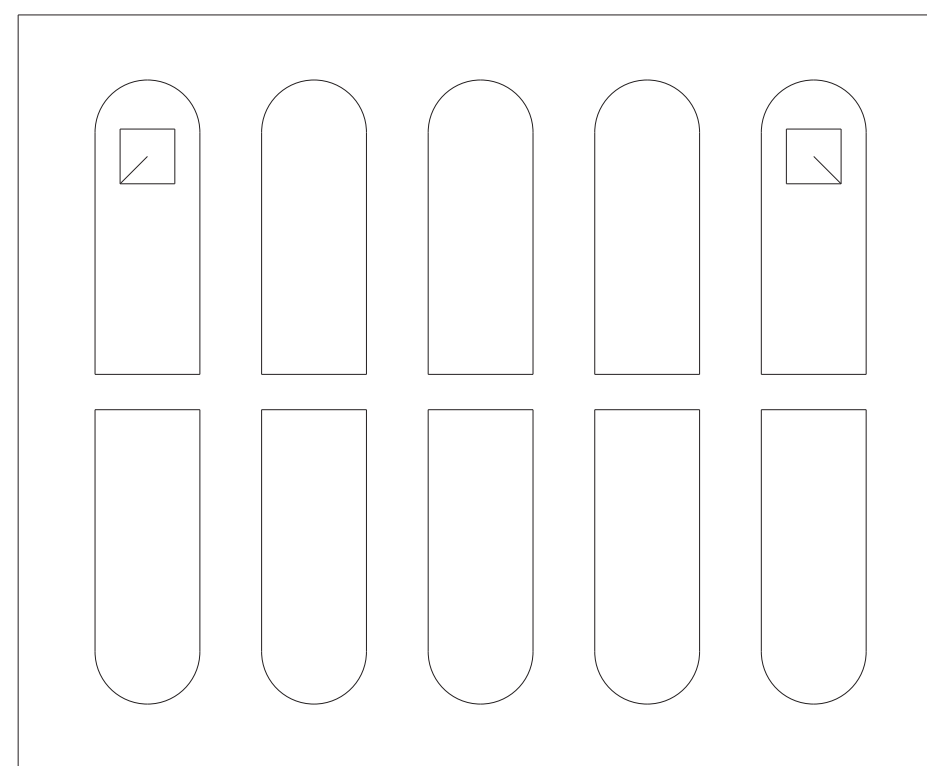
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- Things to avoid during Absorica treatment.
- Ways to get more information if you need it.



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.

/s/

TATIANA OUSSOVA
06/28/2024 03:55:45 PM