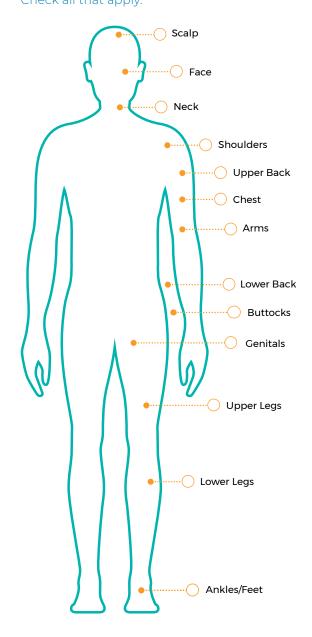


# Talking to your healthcare professional about treatment with DUOBRII Lotion

Once on treatment, talking to your healthcare provider (HCP) is key. Of course, thinking about everything you want to say isn't always easy. We've created this discussion guide to help you get your thoughts together ahead of time. Answer the questions below and bring it to your doctor's office at your next visit.

Name:
When were you prescribed DUOBRII?
How quickly did you see results with DUOBRII?
How often do you use DUOBRII?
What else are you using to treat your psoriasis (prescriptions or over the counter medicines), including any moisturizers?
Questions to ask your doctor  Has DUOBRII been effective in my treatment of plaque psoriasis?
Should I continue to use DUOBRII daily?
What can I expect if I stop using DUOBRII?

Where do you still have plaques? Check all that apply.





My notes & additional questions

#### What is DUOBRII™ Lotion?

DUOBRII (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045%, is a prescription medicine used on the skin (topical) to treat adults with plaque psoriasis. It is not known if DUOBRII Lotion is safe and effective in children.

# **Important Safety Information**

• DUOBRII Lotion is for use on the skin only; do not use it in your mouth, eyes, or vagina.

What is the most important Information I should know about DUOBRII?

DUOBRII Lotion may cause birth defects if used during pregnancy.

A negative pregnancy test must be obtained before females of child-bearing age start using DUOBRII Lotion and they must use effective birth control during treatment. Begin treatment during a normal menstrual period.

Stop using DUOBRII Lotion and tell your healthcare provider right away if you become pregnant while using DUOBRII Lotion.

Before you use DUOBRII Lotion, tell your healthcare provider if you:

- have eczema or any other skin problems, including skin infections, which may need to be treated before using DUOBRII.
- have diabetes, adrenal gland problems or liver problems.
- are breastfeeding or plan to breastfeed. If you use DUOBRII and breastfeed, do not apply DUOBRII to your nipple area.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- Especially tell your healthcare provider if you take corticosteroids by mouth or injection or use other skin products that contain corticosteroids.
- · Ask your healthcare provider for a list of medicines that may make your skin more sensitive to sunlight.

#### What should I avoid during treatment with DUOBRII?

- To avoid a severe sunburn, avoid sunlight, including sunlamps and tanning beds, as much as possible, and use sunscreen, protective clothing and a hat while in sunlight. Talk to your healthcare provider if you get sunburn, and do not use DUOBRII Lotion until your sunburn is healed.
- Avoid using DUOBRII on skin with eczema because it may cause severe irritation.

#### DUOBRII may cause side effects, including:

- If too much DUOBRII passes through your skin it can cause adrenal glands to stop working
- Cushing's syndrome, a condition from too much exposure to the hormone cortisol
- · High blood sugar (hyperglycemia)
- · Effects of growth and weight in children
- Skin irritation. If you get too much skin irritation at the site of application, your healthcare provider may tell you to interrupt or stop using DUOBRII or to use it less often.
- Vision problems, including an increased chance of developing cataracts and glaucoma. Tell your healthcare provider about any vision problems during treatment.

The most common side effects of DUOBRII Lotion include: redness, itching, swelling, burning, stinging, application site pain, inflamed hair follicles (folliculitis), thinning of the skin (atrophy), peeling and rash.

To report SUSPECTED ADVERSE REACTIONS, contact Ortho Dermatologics at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please <u>click here</u> for full Prescribing Information, including Patient Information.





# PATIENT INFORMATION DUOBRII™ (DEW-oh-bree)

(halobetasol propionate and tazarotene) lotion, for topical use

Important information: DUOBRII is for use on skin only. Do not apply DUOBRII in your mouth, eyes, or vagina.

What is the most important information I should know about DUOBRII?

DUOBRII may cause birth defects if used during pregnancy.

Females must not be pregnant when they start using DUOBRII or become pregnant during treatment with DUOBRII.

- For females who are able to get pregnant:
  - O Your healthcare provider will order a pregnancy test for you within 2 weeks before you begin treatment with DUOBRII to be sure that you are not pregnant. Your healthcare provider will decide when to do the test.
  - Begin treatment with DUOBRII during a normal menstrual period.
  - O Use an effective form of birth control during treatment with DUOBRII. Talk with your healthcare provider about birth control options that may be used to prevent pregnancy during treatment with DUOBRII.
  - Stop using DUOBRII and tell your healthcare provider right away if you become pregnant during treatment with DUOBRII.

#### What is DUOBRII?

DUOBRII is a prescription medicine used on the skin (topical) to treat adults with plaque psoriasis.

It is not known if DUOBRII is safe and effective in children under 18 years of age.

#### Do not use DUOBRII if you:

are pregnant. See "What is the most important information I should know about DUOBRII?".

### Before using DUOBRII, tell your healthcare provider about all of your medical conditions, including if you:

- have eczema or any other skin problems.
- have a skin infection. You may need medicine to treat the skin infection before using DUOBRII.
- have diabetes.
- have adrenal gland problems.
- have liver problems.
- are breastfeeding or plan to breastfeed. It is not known if DUOBRII passes into your breast milk. If you use DUOBRII and breastfeed, do not apply DUOBRII to your nipple or areola to avoid getting DUOBRII into your baby's mouth.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take corticosteroids by mouth, or injection, or use other products on your skin that contain corticosteroids.

Certain medicines may make your skin more sensitive to sunlight. Ask your healthcare provider for a list of these medicines if you are not sure.

#### How should I use DUOBRII?

- Use DUOBRII exactly as your healthcare provider tells you to use it.
- If you shower or bathe before applying DUOBRII, your skin should be dry before applying the lotion.
- Apply a thin layer of DUOBRII to the affected areas 1 time each day and rub in gently.
- You should not use more than 50 grams of DUOBRII in 1 week.
- Avoid using DUOBRII on your face, groin, or underarms (armpits).
- Do not bandage, wrap, or cover the treated skin area(s) unless your healthcare provider tells you to.

#### What should I avoid during treatment with DUOBRII?

- Avoid sunlight, including sunlamps and tanning beds during your treatment with DUOBRII. DUOBRII can make your skin more sensitive
  to the sun and the light from sunlamps and tanning beds. You could get severe sunburn. Use sunscreen, and wear a hat and clothes that
  cover your skin if you have to be in sunlight.
- Talk to your healthcare provider if you get sunburn during treatment with DUOBRII. If you do get sunburn, do not use DUOBRII until your sunburn is healed.
- Avoid using DUOBRII on skin with eczema because it may cause severe irritation.

#### What are the possible side effects of DUOBRII?

#### **DUOBRII** may cause side effects, including:

- See "What is the most important information I should know about DUOBRII?"
- DUOBRII can pass through your skin. Too much DUOBRII passing through your skin can cause adrenal glands to stop working.
- Cushing's syndrome, a condition that happens when your body is exposed to too much of the hormone cortisol.
- High blood sugar (hyperglycemia).
- Effects of growth and weight in children.
- **Skin irritation**. DUOBRII may cause increased skin irritation. Tell your healthcare provider if you develop any skin irritation during your treatment with DUOBRII. If you develop skin irritation, your healthcare provider may tell you to interrupt or stop using DUOBRII, or tell you to use DUOBRII less often.
- Sensitivity to light and risk of sunburn. See "What should I avoid during treatment with DUOBRII?"
- Vision problems. DUOBRII may increase your chance of developing cataract(s) and glaucoma. Tell your healthcare provider if you have blurred vision or other vision problems during your treatment with DUOBRII.

**The most common side effects of DUOBRII include:** redness, itching, swelling, burning, stinging, application site pain, inflamed hair follicles (folliculitis), thinning of the skin (atrophy), peeling and rash.

These are not all of the possible side effects of DUOBRII.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### How should I store DUOBRII?

- Store DUOBRII at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from freezing.

## Keep DUOBRII and all medicines out of the reach of children.

#### General information about the safe and effective use of DUOBRII

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use DUOBRII for a condition for which it was not prescribed. Do not give DUOBRII to other people, even if they have the same condition you have. It may harm them. You can ask your pharmacist or healthcare provider for information about DUOBRII that is written for health professionals.

#### What are the ingredients in DUOBRII?

Active ingredients: halobetasol propionate and tazarotene

**Inactive ingredients:** carbomer copolymer type B, carbomer homopolymer type A, diethyl sebacate, edetate disodium dihydrate, light mineral oil, methylparaben, propylparaben, purified water, sodium hydroxide, sorbitan monooleate and sorbitol solution, 70%.

Manufactured for: Bausch Health Americas, Inc., Bridgewater, NJ 08807 USA

By: Bausch Health Companies Inc., Laval, Quebec H7L 4A8, Canada

U.S. Patent Numbers: 6,517,847; 8,809,307 and 10,251,895

DUOBRII is a trademark of Bausch Health Companies Inc. or its affiliates.

© 2019 Bausch Health Companies Inc. or its affiliates

For more information call 1-800-321-4576

This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued: 04/2019

9645601