

Batrafen[®] Cream and Solution (bat-rar-fen)

Ciclopirox (sick-low-pir-rocks)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Batrafen.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using it against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Batrafen is used for

Batrafen contains ciclopirox, which is an antifungal agent. Batrafen is used to treat fungal infections of the skin.

Ask your doctor or pharmacist if you have any questions about why it has been recommended for you.

Before you use it

When you must not use it

Do not use Batrafen if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give Batrafen to a child.

Do not use it if you are pregnant or intend to become pregnant.

It may affect your developing baby if you use it during pregnancy.

Do not use it if you are breast-feeding or planning to breast-feed.

Batrafen may pass into breast milk and there is a possibility your baby may be affected.

Do not use Batrafen Cream with latex condoms.

It contains a paraffin which can cause leaking or breaking of latex condoms and therefore lose the protection provided by condoms.

Do not use it after the expiry date (EXP) printed on the pack.

If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn or shows signs of tampering.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Batrafen is not recommended to be used during pregnancy. Your doctor or pharmacist will discuss the risks and benefits of using it if you are pregnant.

Tell your doctor or pharmacist if you are breast-feeding or planning to breast-feed.

It is not known whether Batrafen passes into breast milk. Your doctor or pharmacist will discuss the risks and benefits of using it if you are breast-feeding or planning to breast-feed.

Tell your doctor or pharmacist if you plan to have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you use Batrafen.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

How to use it

How to use it

Apply Batrafen Cream on average twice daily to the affected area and allow to dry.

Apply Batrafen Solution twice daily to the affected areas and rub in gently.

When to use it

If you are not sure when to use it, ask your doctor or pharmacist.

How long to use it

Batrafen Cream

Continue applying Batrafen Cream until the symptoms have disappeared (usually 2 weeks). To prevent the symptoms returning, continue applying for a further 1 to 2 weeks.

Batrafen Solution

Relief of symptoms usually occurs within 1 to 2 weeks of starting treatment with Batrafen Solution.

To prevent the symptoms returning, continue applying Batrafen Solution for a further 1 to 2 weeks.

Ask your doctor or pharmacist if you are not sure how long to use the medicine for.

Speak to your doctor or pharmacist if there has been no improvement in symptoms after 4 weeks.

If you forget to use it

Apply it as soon as you remember, and then go back to using the Cream or Solution as you would normally.

Do not use a double dose to make up for the dose you have missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for hints.

If you use too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have used too much Batrafen.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are using Batrafen.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Batrafen.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using this medicine.

If you become pregnant while you are using this medicine, stop using it and tell your doctor or pharmacist immediately.

Things you must not do

Do not put it inside the mouth or vagina.

Do not apply the Cream or Solution to your eyes.

Never swallow this medicine.

Do not cover the affected area with a bandage after applying the Cream or Solution.

Do not use more than the recommended dose unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop using Batrafen without checking with your doctor or pharmacist.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Batrafen.

It helps most people with fungal infections, but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- skin irritation, redness or rash around the application area.

These are mild side effects of this medicine and usually short-lived.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

After using it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep Batrafen cream in a cool, dry place where the temperature stays below 30°C.

Keep Batrafen solution in a cool, dry place where the temperature stays below 25°C. Protect from light.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car. Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop using Batrafen, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Batrafen Cream is a white cream supplied in a tube.

Batrafen solution is a clear liquid supplied in a plastic bottle.

Ingredients

Batrafen Cream

Active Ingredient:

- ciclopirox 10mg/g

Inactive Ingredients:

- 2-octyldodecanol
- mineral oil
- stearyl alcohol
- cetyl alcohol
- polysorbate 60
- myristyl alcohol
- cocamide DEA
- sorbitan monostearate
- lactic acid
- purified water
- benzyl alcohol

Batrafen Cream does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Batrafen Solution

Active Ingredient:

- ciclopirox 10mg/ml

Inactive Ingredients:

- alcoholic aqueous solution.

Batrafen Solution does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Manufacturer/Sponsor

Batrafen is made in Germany.

Batrafen is supplied in New Zealand by:

sanofi-aventis new zealand limited
Level 8, James and Wells Tower
56 Cawley Street
Ellerslie
Auckland

This leaflet was prepared in June 2009.

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