

Hydrozole Cream

Hydrocortisone (microfine) 1% w/w and clotrimazole 1% w/w

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Hydrozole Cream. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the benefits of you using Hydrozole Cream against the risks he expects it may have for you.

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

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

What is Hydrozole Cream and what is it used for?

Hydrozole Cream contains hydrocortisone (it belongs to the group of medicines called corticosteroids) and clotrimazole (it belongs to a group of medicines called antifungals).

Hydrozole Cream is used on the skin to relieve the redness, swelling, itching and discomfort of many skin problems such as:

- Nappy Rash.
- Candidal infections (a yeast-like micro-organism) where there is also inflammation on the skin.
- Fungal-infected dermatitis.
- Tinea infections such as jock itch and athlete's foot.

Your doctor may have prescribed Hydrozole Cream for another purpose. Ask your doctor if you have any questions about why Hydrozole Cream has been prescribed for you.

Hydrozole Cream is not addictive.

Hydrozole Cream is only available with a doctor's prescription.

Before you use Hydrozole Cream

When you must not use it

Do not use Hydrozole Cream if you have an allergy to:

- any medicine containing hydrocortisone or clotrimazole.
- any of the ingredients listed at the end of this leaflet.
- any other similar medicines (such as medicines of the same class).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use Hydrozole Cream if you have:

- a viral skin infection (such as cold sores, shingles or chicken pox).
- bacterial skin infection such as school sores.
- pruritus (itching skin) without any inflammation or redness.

- rosacea (skin condition of the face where the nose and cheeks are unusually red).
- acne.
- problems with your circulation.
- any other serious infections of the skin.

Ask your doctor to be sure you do not have any of these conditions.

Do not use Hydrozole Cream after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not use Hydrozole Cream just before having a bath, shower or going swimming.

If you do, you may reduce the effectiveness of Hydrozole Cream.

If you are not sure whether you should start taking Hydrozole Cream, contact your doctor or pharmacist.

Before you start to use it

Tell your doctor if:

- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- you are taking any medication containing corticosteroids for other conditions (e.g. asthma, arthritis, organ transplants).
- you have a serious illness affecting your immune system.
- you are pregnant or intend to become pregnant.
Your doctor will discuss the risks and benefits of using Hydrozole Cream when pregnant.

- **you are breastfeeding or intend to breastfeed.**
Your doctor will discuss the risks and benefits of using Hydrozole Cream when breastfeeding.
Do not apply Hydrozole Cream to the breasts before breastfeeding.
- **you have had or have any other medical conditions, including receiving a transplanted organ or HIV.**

If you have not told your doctor about any of the above, tell him before you use Hydrozole Cream.

Using other medicines

Tell your doctor if you are using other creams, ointments or lotions or taking any other medicine. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Hydrozole cream may interfere with each other.

These include:

- **Asthma medication.**
- **Medication for arthritis.**
- **Medication for a recent organ transplant you have received.**
- **Medication for the treatment of HIV.**

These medicines may be affected by Hydrozole cream or affect how well Hydrozole Cream works. You may need to use different amounts of your medicine, or you may need to use different medicines. Your doctor will advise you.

Your doctor may have more information on medicines to be careful with or avoid while using Hydrozole Cream.

How to use Hydrozole Cream

Hydrozole Cream is for external use only.

Follow all directions given to you by your doctor carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, tube or this leaflet, ask your doctor for help.

Gently rub a small quantity of Hydrozole Cream in a thin film into the affected area two times daily for up to 7 days.

Apply enough cream to disappear into the skin without leaving any on the skin.

Wash your hands after use, unless you are treating the hands.

If the location of the skin condition is in an area normally covered with clothing, you should ensure that loose clothing is worn over the affected area to be treated.

It is important to use Hydrozole Cream exactly as your doctor has told you.

If you use it less often than you should, it may not work as well and your skin problem may not improve. Using it more often than you should may not improve your skin problem any faster and may cause or increase side effects.

Use Hydrozole Cream at the same time every day.

How long should you use it for

You should use Hydrozole Cream for as long as your doctor tells you to. The usual treatment is up to 7 days.

If you use Hydrozole Cream for longer than your doctor tells you, the chance of side effects may increase.

Your doctor may ask you to apply a cream containing a single anti-fungal agent for an extra two weeks after the condition (for which you require treatment with Hydrozole Cream) appears to be cured.

You must do this otherwise there might be a chance of the condition returning.

If you are not sure of how long you need to use Hydrozole Cream, talk to your doctor.

If you forget to use it

If it is almost time for your next application of Hydrozole Cream, skip the application you missed and apply the cream when you are next meant to. Otherwise, use it as soon as you remember, and then go back to using your cream as you would normally.

Do not use a double dose to make up for the dose that you missed.

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

If you swallow it

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital if you think that you, or anyone else may have swallowed Hydrozole Cream. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep this telephone number handy.

While you are using Hydrozole Cream

Things you must do

Tell your doctor(s) who is treating you that you are using Hydrozole Cream.

If you feel that Hydrozole Cream is not helping your condition, tell your doctor.

Tell your doctor if for any reason, you have not used Hydrozole Cream exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using Hydrozole Cream, tell your doctor.

Things you must not do

Do not use Hydrozole Cream:

- under air tight or waterproof dressings or on large areas of skin unless your doctor has told you to.
- in the eyes.
- to treat other complaints unless your doctor tells you to.
- for acne.
- on children under 2 years of age unless a doctor has told you to.
- for more than 7 days unless a doctor has told you to.
- in large amounts for a long time.

If you use large amounts for a long time, the chance of absorption through the skin and the chance of side effects may increase. Ask your doctor if you are concerned about the length of time you have been using Hydrozole Cream.

- on skin areas that rub together such as under the arm or in the groin area unless your doctor tells you to.

Do not wear tight fitting clothing in the area being treated with Hydrozole Cream.

Do not give Hydrozole Cream to anyone else, even if they have the same symptoms as yours.

Do not dilute Hydrozole cream.

Things to be careful of

The ingredients in Hydrozole cream may affect the latex used in barrier contraceptives such as condoms and diaphragms.

You may need to use other methods of contraception whilst using this medicine and for at least 5 days after last using the cream.

If you experience blurred vision or other visual disturbances, speak to your doctor

Take care when applying Hydrozole cream to the eyelids to make sure it does not get into your eye.

If you accidentally get Hydrozole cream in your eyes, wash them well with water.

Side effects

Tell your doctor if you do not feel well while you are using Hydrozole Cream.

Hydrozole Cream helps most people with skin problems but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of these side effects.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following side effects near or on the area you apply Hydrozole Cream and they worry you.

Do not be alarmed by the list of side effects, which follows; you may not experience any of them.

- Drying, cracking, blistering, peeling, thinning, tightening or redness of the skin.
- Burning or stinging feeling on the skin.
- Bruising of the skin.
- Acne-type lumps on the skin.
- Itching or irritation of skin.
- Changes to the colour of your skin.
- Rash or blisters.
- Skin condition getting worse.
- Other obvious unexpected changes to the skin area treated.

These side effects are usually mild.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- if your skin condition gets worse or your skin becomes swollen during treatment, you may be allergic to the medicine, have an infection or need other treatment.
- wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Very rare side effects that may show up in blood tests or when your doctor gives you a medical examination:

- a decrease in the level of the hormone cortisol in your blood
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (cataract)
- increased pressure in the eye (glaucoma)
- weakening of the bones through gradual loss of mineral (osteoporosis) - additional tests may be needed after your medical examination to confirm if you have this condition.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor if you don't understand anything in this list.

After using Hydrozole Cream

Storage

Keep Hydrozole Cream in a cool dry place where the temperature stays below 25°C.

Do not store Hydrozole Cream or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Do not refrigerate Hydrozole Cream.

Keep Hydrozole Cream where young 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 tells you to stop using Hydrozole Cream or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Supplier

Hydrozole Cream is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Consumer Healthcare Division
82 Hughes Ave,
Ermington NSW 2115
Australia

**Australian Registration Number:
AUST R 10319**

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Hydrozole is a registered trade mark of Stiefel Laboratories, Inc.

Version 5.0

Product Description

What it looks like

Hydrozole Cream is a smooth, non-greasy white cream, which is available in a 50 gram tube in a carton.

Ingredients

The active ingredients in Hydrozole Cream are hydrocortisone 1% and clotrimazole 1%.

Hydrozole Cream also contains the following inactive ingredients:

- cetomacrogol 1000
- glycerin
- cetostearyl alcohol
- light liquid paraffin
- white soft paraffin
- propylene glycol
- chlorocresol 0.2% (as a preservative)
- purified water
- sodium hydroxide
- lactic acid

Hydrozole Cream does not contain lanolin, paraben preservatives or fragrances and washes off with water.