Retrieve® Cream

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Retrieve?

Retrieve contains the active ingredient tretinoin. Retrieve is used for the treatment of dry, sun-damaged skin.

For more information, see Section 1. Why am I using Retrieve? in the full CMI.

2. What should I know before I use Retrieve?

Do not use if you have ever had an allergic reaction to Retrieve or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Retrieve? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Retrieve and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Retrieve?

- The usual dose is to apply a thin layer to the affected skin area(s).
- Apply once a day before going to bed.
- Carefully follow the exact instructions given to you by your doctor or pharmacist.

More instructions can be found in Section 4. How do I use Retrieve? in the full CMI.

5. What should I know while using Retrieve?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Retrieve. Protect your skin when you are in the sun. If you are outdoors, wear protective clothing and apply a broad-spectrum 30+ SPF sunscreen. Reapply sunscreen regularly.
Things you should not do	 Do not apply to the eyes, around eyelids, mouth, lips, mucosa, or angles of the nose. Do not apply other skin preparations on top of the nightly application. Do not apply more often than or longer time than what your doctor has told you. Do not use to treat any other complaint unless your doctor tells you to. Do not use any skin treatments, such as skin peels or medicated dressing on the same affected areas unless your doctor has told you to. Do not mix with any other preparations. Do not swallow this medicine.
Looking after your medicine	Store it in a cool dry place where the temperature is below 25°C, away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while using Retrieve? in the full CMI.

6. Are there any side effects?

Common and less-serious side effects include redness of skin, feeling of warmth on skin, peeling of skin, slight stinging and darkening or lightening of the treated areas.

Serious side effects include excessive irritation, severe burning and the skin becomes very sensitive to light.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Retrieve® Cream

Active ingredient: Tretinoin 0.5 mg/g

Consumer Medicine Information (CMI)

This leaflet provides important information about using Retrieve. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Retrieve.

Where to find information in this leaflet:

- 1. Why am I using Retrieve?
- 2. What should I know before I use Retrieve?
- 3. What if I am taking other medicines?
- 4. How do I use Retrieve?
- 5. What should I know while using Retrieve?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Retrieve?

Retrieve contains the active ingredient Tretinoin.

Tretinoin is the acid form of Vitamin A.

Retrieve is used for the treatment of dry, sun-damaged skin.

Retrieve works by regulating the growth and regeneration of the outer layer of the skin.

Your doctor may have prescribed Retrieve for another reason. Ask your doctor if you have any questions why Retrieve has been prescribed for you.

2. What should I know before I use Retrieve?

Warnings

Do not use Retrieve if:

 You are allergic to tretinoin, isotretinoin, vitamin A, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- The packaging is torn or shows signs of tampering

Check with your doctor if you have:

- any other medical conditions including:
 - sunburn. Delay the use of Retrieve until the skin is fully recovered.
 - other forms of skin disease such as eczema. Delay use of Retrieve until the eczema has cleared or use with caution. Retrieve can cause severe irritation on eczema.
 - o sensitive skin.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

- Do not use Retrieve if you pregnant or planning a pregnancy.
- Stop using Retrieve immediately if you fall pregnant and see your doctor.
- Tell your doctor if you are breastfeeding or wish to breastfeed. It is not known whether Retrieve passes into breastmilk.

3. What if I am taking other medicines?

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

Some medicines may interfere with Retrieve and affect how it works.

These include:

- Medicines and skin preparations used to treat acne.
- Skin preparations containing peeling agents (e.g., resorcinol, sulfur, salicylic acid, or benzoyl peroxide).
- Skin preparations containing vitamin A.
- Medicines which can increase sun sensitivity including some antibiotics, diuretics, and antipsychotic medicines
- Cosmetics, perfumes, or astringents (e.g., aftershave, skin toner) especially those containing high concentration of alcohol, spices, lime, or menthol.
- Abrasive powders, scrubbing agents, soaps, shampoos, or cleansers.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Retrieve.

4. How do I use Retrieve?

How much to use

- Apply a thin layer to the affected skin area(s).
- Follow the instructions provided below and use Retrieve until your doctor tells you to stop.

When to use Retrieve

Retrieve should be used once a day before going to bed.

How to use Retrieve

Carefully follow the exact instructions given to you by your doctor or pharmacist. These may differ from the information contained in this CMI.

- If you are using a new tube, unscrew the cap and check that the aluminium seal is intact. To break the seal, reverse the cap and pierce through.
- Wash the affected areas with a mild soap-free cleanser and lukewarm water. Pat dry.
- Apply the cream to the affected skin. Massage in gently.

- Wash hands thoroughly with water after each application.
- Only use Retrieve on intact skin. Be careful to avoid contact with your eyes, mouth, lips, angles of the nose and open wounds. Do not swallow.

The treatment program is to be started slowly. The usual dosage regimen is as follows:

- First night Apply, leave on for 5 minutes, then wash off.
- Second night Apply, leave on for 10 minutes, then wash off.
- Third night Apply, leave on for 30 minutes, then wash off
- Fourth night Apply, leave on for one hour, then wash off
- Fifth night Apply, leave on for one and a half hours, then wash off.
- Sixth night Apply, leave on for two hours, then wash off.
- If after a two-hour application, no redness or irritation has developed on the skin the following day, then the application may be left on overnight and washed off next morning.
- If there is redness or irritation, check with your doctor.

Your doctor will assess how your skin responds to treatment, and how well it tolerates the medication. If excessive skin reactions occur, your doctor may adjust the application to alternate nights or temporarily discontinue treatment.

At your next visit, your doctor will review how your skin is responding to treatment. Your doctor will decide on the best course of treatment according to your skin condition and response. This may change from time to time depending on your medical condition.

Ask your doctor or pharmacist on how to apply Retrieve if you are not sure.

If you forget to use Retrieve

Use Retrieve regularly at the same time each day. If you miss your dose at the usual time, apply the medicine when you remember, and then go back to using it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much Retrieve

If you think that you have applied too much Retrieve, remove any excess cream.

Do not take this medicine by mouth. If you or someone else accidentally swallows some Retrieve, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 [0800 POISON] in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Retrieve?

Things you should do

- Contact your doctor or pharmacist immediately if you notice any unusual symptoms (such as a rash) during treatment.
- Tell your doctor if, for any reason, you have not used your medicine exactly as directed.
- Protect your skin when you are in the sun. If you are outdoors, wear protective clothing and apply a broadspectrum SPF 30+ or higher sunscreen. Reapply sunscreen regularly.

Call your doctor straight away if you:

- Become pregnant while you are using Retrieve.
- Notice any excessive skin reaction and unusual symptoms (such as a rash).

Remind any doctor, dentist or pharmacist you visit that you are using Retrieve.

Things you should not do

- Do not apply to the eyes, around eyelids, mouth, lips, mucosa, or angles of the nose.
- Do not apply other skin preparations on top of the nightly application of Retrieve. Suitable sunscreens and moisturisers may be used during the day.
- Do not apply more often than or longer time than what your doctor has told you.
- Do not use Retrieve to treat any other complaint unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the similar symptoms to yours.
- Do not use any skin treatments, such as skin peels or medicated dressing on the same affected areas unless your doctor has told you to.
- Do not mix Retrieve with any other preparations. They may prevent Retrieve from working.
- Do not swallow this medicine.

Things to be careful of:

- Sunlight/Solarium avoid exposure of the treated area
 to excessive sunlight or overuse of a sunlamp because
 your skin may be more prone to sunburn whilst using
 Retrieve. When exposed to sunlight use at least a 30+
 SPF broad-spectrum sunscreen and wear protective
 clothing over the treated areas.
- Strong Wind/Dry Air These may cause skin discomfort.
 Apply moisturiser or emollient if this occurs. Check with your doctor or pharmacist about suitable wind protection if you notice any unusual rash or redness.
- Cosmetics Check with your doctor or pharmacist which cosmetics or perfumed toiletries you can use. Wash any cosmetics off any affected areas before you apply Retrieve.
- Washing your face Avoid using harsh soaps or exfoliants. Use a mild bland soap, or any suitable soap free cleansers.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature is below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 redness of skin feeling of warmth on skin peeling of skin slight stinging darkening or lightening of the treated areas. 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 excessive irritation severe burning the skin becomes very sensitive to light. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side affects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia, or Medsafe at www.medsafe.govt.nz/safety/report-a-problem.asp in New Zealand.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Retrieve contains

Active ingredient (main ingredient)	Tretinoin
Other ingredients (inactive ingredients)	 cetyl alcohol isopropyl palmitate self-emulsifying glyceryl monostearate sorbitan monostearate polysorbate 60 disodium edetate dl-alpha-tocopheryl acetate retinol palmitate methyl hydroxybenzoate propyl hydroxybenzoate diazolidinyl urea propylene glycol purified water
Potential allergens	methyl hydroxybenzoatepropyl hydroxybenzoatediazolidinyl urea

Do not take this medicine if you are allergic to any of these ingredients.

What Retrieve looks like

Retrieve is a smooth off-white to pale yellow cream contained in an aluminium tube with an outer carton and is available in the following pack sizes:

- 5g tube
- 50g tube

(AUST R 15553).

Who distributes Retrieve

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

iNova Pharmaceuticals (New Zealand) Pty Limited

Auckland

Tel: 0508 375 394

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