ADAPAX™ 0.1%/2.5%

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 ADAPAX™ 0.1%/2.5%?

ADAPAX™ 0.1%/2.5% contains the active ingredients adapalene and benzoyl peroxide.

ADAPAX™ 0.1%/2.5% is used on the skin to treat acne.

For more information, see Section 1. Why am I using ADAPAX™ 0.1%/2.5%? in the full CMI.

2. What should I know before I use ADAPAX™ 0.1%/2.5%?

Do not use if you have ever had an allergic reaction to ADAPAX™ 0.1%/2.5% 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 ADAPAX™ 0.1%/2.5%? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ADAPAX™ 0.1%/2.5% 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 ADAPAX™ 0.1%/2.5%?

- The usual dose of ADAPAX™ 0.1%/2.5% is an application of a thin layer of gel once daily. Wash the affected area, rinse with warm water then lightly pat dry the skin. Apply a thin layer of gel to the area of the skin that has acne and not just the individual spots.

More instructions can be found in Section 4. How do I use ADAPAX™0.1%.2.5%? in the full CMI.

5. What should I know while using ADAPAX™ 0.1%/2.5%?

Things you should do	• If you become pregnant while using this medicine, tell your doctor immediately. • Avoid excessive exposure to sunlight and sunlamps. • Avoid using any products on the skin which could irritate or dry it out (e.g., medicated or abrasive soaps & cleansers, products with a high alcohol content). • Tell your doctor if you feel that ADAPAX™ 0.1%/2.5% is not helping your condition. • Remind any doctor, dentist or pharmacist you visit that you are using ADAPAX™ 0.1%/2.5%.
Things you should not do	• You should not give ADAPAX™ 0.1%/2.5% to anyone else, even if they have the same condition as you. • You should not use ADAPAX™ 0.1%/2.5% to treat any other complaints unless your doctor tells you.
Driving or using machines	• ADAPAX™ 0.1%/2.5% has no, or a negligible, effect on the ability to drive and use machines.
Looking after your medicine	• Store below 25°C, and do not store ADAPAX™ 0.1%/2.5% in the refrigerator.

For more information, see Section 5. What should I know while using ADAPAX™ 0.1%/2.5% in the full CMI.

6. Are there any side effects?

Very common side effects include: dry skin; skin irritation; skin burning sensation; skin scaling; reddening of the skin.

Uncommon side effects include: sunburn; itching.

Other reported side effects include: allergic reaction; face swelling; difficulty breathing (dyspnoea); throat tightness; swollen eyelids; stinging skin pain; blisters; discoloured skin; hives; skin burn at the site of application.

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.

ADAPAX™ 0.1%/2.5%

Active ingredient(s): *Adapalene 0.1% w/w and benzoyl peroxide 2.5% w/w*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ADAPAX™ 0.1%/2.5%. **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 ADAPAX™ 0.1%/2.5%.**

Where to find information in this leaflet:

1. Why am I using ADAPAX™ 0.1%/2.5%?
2. What should I know before I use ADAPAX™ 0.1%/2.5%?
3. What if I am taking other medicines?
4. How do I use ADAPAX™ 0.1%/2.5%?
5. What should I know while using ADAPAX™ 0.1%/2.5%?
6. Are there any side effects?
7. Product details

1. Why am I using ADAPAX™ 0.1%/2.5%?

ADAPAX™ 0.1%/2.5% contains the active ingredients adapalene and benzoyl peroxide.

These two active ingredients work in different but complementary ways.

Adapalene is a topical retinoid – its main actions are to normalise skin cell development, prevent pores from being blocked and promote skin renewal.

Benzoyl peroxide kills bacteria (antibacterial) and also works by softening and peeling the outer layer of the skin.

Adapalene and benzoyl peroxide work together to rapidly reduce inflammation.

ADAPAX™ 0.1%/2.5% is used to treat acne. It is used on the face, chest or back.

Your doctor, however, may prescribe ADAPAX™ 0.1%/2.5% for another purpose.

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

2. What should I know before I use ADAPAX™ 0.1%/2.5%?

Warnings

ADAPAX™ 0.1%/2.5% contains benzoyl peroxide which may cause bleaching and discolouration to the hair and dyed fabrics.

Do not use ADAPAX™ 0.1%/2.5%:

- If you are allergic to adapalene, benzoyl peroxide or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- on areas where you have cuts, scrapes or eczema, or on sunburned skin.
- **during pregnancy.** If you fall pregnant while using ADAPAX™ 0.1%/2.5%, you must stop using it and tell your doctor as soon as possible, for further follow-up.
- on your chest if you are breastfeeding.
- on children under 12 years of age.

Check with your doctor if you:

- are allergic to any other medicines or other substances such as foods, dyes or preservatives.
- have or have had any other health problems.
- plan to become pregnant or to breastfeed.

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

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

4. How do I use ADAPAX™ 0.1%/2.5%?

How much ADAPAX™ 0.1%/2.5% to use

- A thin film of gel evenly over the entire acne-affected area(s) once a day. If applying to the face, avoid the eyes and lips.
- Follow the instructions provided and use ADAPAX™ 0.1%/2.5% until your doctor tells you to stop.

When to use ADAPAX™ 0.1%/2.5%

ADAPAX™ 0.1%/2.5% should be used once a day.

How to use ADAPAX™ 0.1%/2.5%

- Cleanse the skin before applying ADAPAX™ 0.1%/2.5% – a non-soap cleanser is useful. Allow the skin to dry completely before applying ADAPAX™ 0.1%/2.5%.

- Apply a thin film of gel evenly over the entire acne-affected area(s) once a day, on clean and dry skin. If applying to the face, avoid the eyes and lips.
- Wash your hands afterwards.

If the product enters the eye, wash immediately with luke-warm water.

Depending on your condition and how you react to ADAPAX™ 0.1%/2.5%, your doctor may ask you to use it differently.

If you feel that the effect of ADAPAX™ 0.1%/2.5% is too strong or too weak, talk to your doctor or pharmacist.

If you experience irritation when applying ADAPAX™ 0.1%/2.5%, a noncomedogenic moisturiser applied daily may help reduce this sensation. If symptoms persist, speak to your doctor or pharmacist. You may be asked to use the gel less often or to stop for a short time.

If you use more ADAPAX™ 0.1%/2.5% than you should on your skin, you will not get rid of your acne quicker, but your skin may become irritated and red.

If you forget to use ADAPAX™ 0.1%/2.5%

ADAPAX™ 0.1%/2.5% should be used regularly at the same time each day.

If you miss your dose at the usual time, use it as soon as you remember.

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

If you use too much ADAPAX™ 0.1%/2.5%

ADAPAX™0.1%/2.5% is for external use only.

If swallowed, you should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 ADAPAX™ 0.1%/2.5%?

Things you should do

Call your doctor straight away if you:

- become or plan to become pregnant while using ADAPAX™ 0.1%/2.5%.

Remind any doctor, dentist or pharmacist you visit that you are using ADAPAX™ 0.1%/2.5%.

Things you should not do

- Do not give ADAPAX™ 0.1%/2.5% to anyone else, even if they have the same condition as you.
- Do not use ADAPAX™ 0.1%/2.5% to treat any other medical complaints unless your doctor tells you to.

Things to be careful of

When using ADAPAX™ 0.1%/2.5% on the face, don't get it into your eyes, mouth or nostrils, and avoid other very sensitive areas of the body.

Other acne products (containing benzoyl peroxide and / or retinoids) should not be used with ADAPAX™ 0.1%/2.5%.

Avoid waxing as a means of hair removal on the skin treated with ADAPAX™ 0.1%/2.5%.

Avoid using other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have strong skin-drying effect and products with high concentrations of alcohol, astringents, spices, or limes) while being treated with ADAPAX™ 0.1%/2.5%.

Cosmetics with irritant or drying effect should not be used with ADAPAX™ 0.1%/2.5%.

ADAPAX™ 0.1%/2.5% contains propylene glycol (E1520) that may cause skin irritation.

Avoid excessive exposure to sunlight and UV lamps. Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a non-comedogenic, broad spectrum, SPF 50+ sunscreen.

Looking after your medicine

Follow the instructions on the packaging on how to store ADAPAX™ 0.1%/2.5% properly.

ADAPAX™ 0.1%/2.5% should be stored in a cool dry place 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 windowsills.

Do not store ADAPAX™ 0.1%/2.5% in a refrigerator.

Store ADAPAX™ 0.1%/2.5% where children cannot reach it.

When to discard ADAPAX™ 0.1%/2.5%

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.

If skin irritation appears after the application of ADAPAX™ 0.1%/2.5%, the intensity is generally mild or moderate with some local symptoms (redness, dryness, scaling, stinging and burning) peaking during the first two weeks and then subsiding spontaneously.

Less serious side effects

Less serious side effects	What to do
More common side effects: • dry skin • irritative contact dermatitis (skin irritation) • skin burning sensation • skin exfoliation (scaling) • superficial reddening of skin More uncommon side effects: • sunburn • itching	**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
• allergic contact dermatitis (local allergic reaction) • swelling face • dyspnoea (difficulty breathing) • throat tightness • swollen eyelids • pain of skin (stinging pain) • blisters (vesicles) • skin discolouration • urticaria (hives) • anaphylactic reaction (a potentially severe allergic reaction) • application site burn	**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 effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. 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

ADAPAX™ 0.1%/2.5% is only available with a doctor's prescription.

What ADAPAX™ 0.1%/2.5% contains

Active ingredients (main ingredients)	adapalene 0.1% w/w benzoyl peroxide 2.5% w/w
Other ingredients (inactive ingredients)	• disodium edetate • docusate sodium • glycerol • poloxamer • propylene glycol • sorbitan oleate • purified water • acrylamide / sodium acryloyldimethyl taurate copolymer • isohexadecane • polysorbate 80

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

What ADAPAX™ 0.1%/2.5% looks like

ADAPAX™ 0.1%/2.5% is a white to very pale-yellow opaque gel.

ADAPAX™ 0.1%/2.5% is available in a bottle (pump pack) containing 30 g.

AUST R 427930

Who distributes ADAPAX™ 0.1%/2.5%

Nova Pharmaceuticals Australasia Pty Ltd

Suite 305, 10 Norbrik Drive,

Bella Vista NSW 2153

Ph: 1800 002 171

www.novapharm.com.au

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