

ADACIN GEL
Adapalene and Clindamycin Phosphate Gel

Patient Information Leaflet

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

1. What Adacin Gel is and what it is used for
2. What you need to know before you use Adacin Gel
3. How to use Adacin Gel
4. Possible side effects
5. How to store Adacin Gel
6. Contents of the pack and other information

1. What Adacin Gel is and what it is used for

Adacin Gel contains two medicines: Clindamycin and Adapalene which work together but in different ways

- Clindamycin is an antibiotic which stops the bacteria involved in acne from reproducing
- Adapalene, which has an anti-inflammatory effect reducing soreness and irritation.

Used together in Adacin Gel, these work by:

- Fighting the bacteria that can cause acne
- Treating existing blackheads, whiteheads, and spots
- Lowering the number of red, inflamed acne spots

Adacin Gel is used for treating mild to moderate acne on your skin.

2. What you need to know before you use Adacin Gel

Do not use Adacin:

- If you are allergic to adapalene, clindamycin or any of the other ingredients of this medicine
- Do not use Adacin Gel if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before you start using Adacin Gel.

Warnings and precautions

Talk to your doctor or pharmacist before using Adacin Gel.

- Do not use this medicine on areas where you have cuts or scrapes or if you have a skin condition called eczema.
- Avoid contact with the eyes, mouth or nostrils, and avoid other very sensitive areas of the body. If accidental contact does occur, immediately wash with warm water.
- If you experience sensitivity or irritation when applying this medicine, stop using it and tell your doctor. You may be asked to use the gel less often, or to stop using it until symptoms subside.

- You should avoid exposure to sunlight and artificial UV light whilst using Adacin Gel.
- Do not use too much Adacin Gel on sensitive areas of skin.
- Most patients will experience some skin redness and peeling during the first few weeks of treatment. If your skin becomes irritated, you may need to use an oil-free moisturiser, use Adacin Gel less often, or stop using it for a short period to allow your skin to recover and then re-start treatment.
- Stop treatment and see your doctor if skin irritation is severe (severe redness, dryness, itching, stinging or burning) or does not improve.

Check with your doctor or pharmacist before using this medicine if:

- You have ever had any of the following gut problems: 'regional enteritis', 'ulcerative colitis', or 'antibiotic-associated colitis'.
- You develop stomach cramps or diarrhoea that does not improve or is severe, stop using Adacin Gel and contact your doctor immediately. Antibiotics may cause a condition that results in severe diarrhoea and stomach cramps although this is unlikely to happen with antibiotics applied to the skin.
- If you have recently used other clindamycin or erythromycin containing medicines, there is an increased chance that Adacin Gel will not work as well as it should.
- Tell your doctor or pharmacist if you have used any other clindamycin or erythromycin containing medicines recently.

Children

Do not give this medicine to children under twelve years. It is not known if it works or if it is safe for them.

Other medicines and Adacin Gel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Do not use other acne products (containing benzoyl peroxide) at the same time as Adacin Gel. You may need to use the two products at different times of the day (e.g. one in the morning and the other in the evening). This is because when used together with Adacin Gel, they may irritate your skin over time.

Adacin Gel may make some acne medicines less effective when used at the same time.

- Avoid using Adacin gel at the same time as cosmetics that are irritant, drying or exfoliate the skin.
- Avoid using medicated or 'abrasive' soaps and cleansers, products which contain large amounts of alcohol or 'astringents'.
- If you are going to hospital for a surgical procedure, tell your doctor and/or anaesthetist if you are taking drugs that cause paralysis of muscle (neuromuscular blocking agents).

Pregnancy and breast-feeding

There is only limited information about the safety of Adacin Gel in pregnant women.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Your doctor will consider the benefit to you and the risk to your baby of using Adacin Gel while you're pregnant.

It is not known whether the ingredients of Adacin Gel can pass into breast milk. One of the medicines in Adacin Gel is clindamycin.

When clindamycin is taken by mouth or injection, it may pass into breast milk.

If you are breast-feeding, you must check with your doctor before you use Adacin Gel.

Do not use Adacin Gel on your breast if you are breast-feeding

Driving and using machines

No effects on the ability to drive or use machines have been seen with Adacin Gel

3. How to use Adacin Gel

This medicine is for EXTERNAL USE ONLY.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Use Adacin Gel is applied at night before going to bed, unless your doctor has told you otherwise.
- Adacin Gel is only intended for use in adults and adolescents aged 12 years and over.
- Your doctor will tell you how long you will need to use Adacin Gel

How to apply Adacin Gel

1. Completely remove any make-up.
2. Wash the affected area of skin well. Then rinse with warm water and gently pat dry.
3. Put a thin film of gel on the entire area of affected skin, using your fingertips.
4. Apply to all of the areas of your skin which have acne, not just to the individual spots.
5. If you get a lot of dryness or skin peeling, you can use an oilfree, fragrance free, hypoallergenic moisturiser, use Adacin

Gel less frequently or stop treatment for a short period, to allow your skin to adjust to the treatment. This medicine may not work properly if it is not applied every day.

6. Wash your hands after using the gel.
7. After it has dried, you can use a non-greasy make-up.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you use more Adacin Gel than you should

- Take care not to apply too much. Applying too much gel or applying it more frequently will not help your spots clear up more quickly, and may cause skin irritation. If this does happen, use the gel less often, or stop using it for a few days and then start again.

If you accidentally swallow Adacin Gel

- If you do accidentally swallow the gel, seek medical advice. You may get symptoms similar to when you take antibiotics by mouth (an upset stomach).

If you forget to use Adacin Gel

- Do not use a double dose to make up for forgotten individual doses.
- Apply the next dose at the usual time.

Don't stop Adacin Gel without advice

Don't use the gel for more than 12 weeks at one time, without talking to your doctor. Use Adacin Gel for as long as your doctor recommends. Don't stop unless your doctor advises you to.

It is important to continue to use the gel as prescribed by your doctor. If you stop too soon, your acne may return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Adapalene in Adacin Gel may cause the following side effects at the site of application.

Common: may affect up to 1 in 10 people

- dry skin
- irritation of the skin
- burning sensation of the skin
- redness of the skin (erythema)

Uncommon: may affect up to 1 in 100 people

- local skin reaction (contact dermatitis)
- skin discomfort
- sunburn
- itching of the skin (pruritus)
- peeling skin (exfoliation)
- acne

Not known: frequency cannot be estimated from the available data

- allergic contact reaction
- pain or swelling of the skin
- irritation, redness, itching or swelling of the eyelids

Clindamycin in Adacin Gel may cause the following side effects at the site of application

Very common: may affect more than 1 in 10 people

- Skin irritation (may cause symptoms such as burning, itching, peeling), hives, dryness of skin

Common: may affect up to 1 in 10 people

- Oily skin

Frequency not known, but may also occur

- Severe acne (also known as gram-negative folliculitis), stinging of the eye, stomach pain, inflammation of the skin caused by contact with irritants or allergens
- may cause gastrointestinal disturbances (with symptoms such as diarrhoea and nausea)

Stop using Adacin Gel and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- signs of an allergic reaction (such as swelling of your face, eyes, lips or tongue, nettle rash or difficulty breathing, collapse)
- severe or prolonged diarrhoea, or abdominal cramps
- severe burning, peeling, or itching

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects

5. How to store Adacin Gel

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the tube and carton. The expiry date refers to the last day of that month.
- Keep the medicine in its original container. Store below 30°C.

Do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Adacin Gel contains:

The active substance: Adapalene BP and Clindamycin Phosphate BP

List of Excipients:

Methyl Hydroxybenzoate, Phenoxyethanol, Disodium Edetate, Carbomer 934P, Polysorbate 80, Polyethylene Glycol, Sodium Hydroxide, Propylene Glycol, Fragrance RSGR 130913, Purified water..

What Adacin Gel looks like and content of the pack

Off white coloured opaque smooth homogenous gel.

15 gm gel filled in laminated tube. 1 tube in a carton along with patient information leaflet.

Manufacturing Authorization Holder	Manufacturer
Ajanta Pharma Limited Ajanta House, Charkop Kandivli (West) Mumbai - 400 067, India. Tel : 022-6913 2111/2112 Fax : 022-6913 2070 Email : info@ajantapharma.com	Ajanta Pharma Limited Mirza-Palashbari Road, Village Kokjhar, Kamrup (R), Guwahati, Assam - 781128, India.

For any information about this medicinal product, please contact Manufacturing Authorization Holder.

DATE OF PUBLICATION OR REVISION

Jun 02, 2023