

PACKAGE LEAFLET: INFORMATION FOR THE USER

SONA

0.1% w/w Gel

ADAPALENE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 or pharmacist • 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 or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What SONA is and what it is used for
2. Before you take SONA
3. How to take SONA
4. Possible side effects
5. How to store SONA

1. WHAT SONA IS AND WHAT IS IT USED FOR

- The active substance in SONA is adapalene, which has an anti-inflammatory effect reducing soreness and irritation.
- It is used on the face, chest or back for acne, where the skin has lots of blackheads, spots and pimples.
- SONA is only absorbed into the body in very small amounts and has little effect, except on the surface of the skin.

2. BEFORE YOU USE SONA

Do not use SONA:

- If you are allergic to adapalene or any of the other ingredients of this medicine.

Warnings and precautions

- 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.

- Avoid exposure to strong sunlight and artificial UV light.
 - 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 for a short time.
- Talk to your doctor or pharmacist if you are not sure.

Other medicines and SONA

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

- Other acne products (containing benzoyl peroxide, erythromycin or clindamycin) may be used with SONA but they must be applied in the morning and SONA at night.
- Cosmetics may be used but they must not cause blackheads or dry the skin.

Pregnancy and breast-feeding

- SONA should not be used during pregnancy. If you fall pregnant while using SONA, the treatment must be discontinued and you should inform your doctor as soon as possible for a further follow-up.
- SONA can be used during breast-feeding. To avoid contact exposure of the infant, application of SONA to the chest should be avoided.

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.

3. HOW TO USE SONA

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

- SONA is only intended for use in adults and adolescents aged 12 years and over.
- This medicine is for EXTERNAL USE ONLY.
- SONA is applied at night before going to bed, unless your doctor has told you otherwise.
- Thoroughly wash the areas to be treated with water. Make sure the skin is clean and dry before using this medicine.
- Put on a thin film of the gel with your fingertips to the affected areas and rub in gently.
- Don't forget to wash your hands afterwards.
- How long you will have to use this medicine will depend on how quickly your acne improves. After you have used this medicine for three months, it is important that you see your doctor. He or she can then check the improvement of your acne.

If you use more SONA than you should or accidentally swallow the gel

- If you put too much SONA on your skin, you will not get rid of your acne any quicker, but your skin may become irritated and red. Some peeling or discomfort could also occur.
- In the rare event that you accidentally swallow any of this medicine, seek medical advice.

If you forget to use SONA

Don't worry if you forget to apply your SONA at the right time. When you remember, start using this medicine again, in the same way as before.

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. SONA 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)
- flare up of 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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SONA

- 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. Do not store above 25°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.