

PATIENT INFORMATION LEAFLET

SKYPARA–500

(Acetaminophen suppositories USP 500 mg)

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

This medicine is available without prescription. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or doctor if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

In this leaflet:

1. What SKYPARA–500 suppositories are and what they are used for
2. What you need to know before you use Skypara suppositories
3. How to use SKYPARA –500 suppositories
4. Possible side effects
5. How to store SKYPARA–500 suppositories
6. Contents of the pack and other information

1. What SKYPARA–500 mg Suppositories are and what they are used for

SKYPARA–500 Suppositories contain a medicine called acetaminophen. This belongs to a group of medicines called pain-killers (analgesics).

SKYPARA – 500 Suppositories are used in children and adults from age 12 years and above (Body weight: 40 kg and above)

They are used to treat pain and high temperature (fever) in children and adults.

They are used in patients when it is difficult to take acetaminophen as tablets or syrup.

2. What you need to know before you use Skypara suppositories

Do not use Skypara suppositories if:

If you are allergic to acetaminophen or to the other ingredient of this medicine (listed in section 6).

Warnings and Precautions:

Talk to your doctor or pharmacist before using these suppositories

- if you have liver or kidney problems.
- if you are taking other medicines which can affect your liver.

Other medicines and Skypara suppositories

Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines, this includes medicines that you buy without a prescription and herbal medicines. This is because Skypara suppositories can affect the way some medicines work and some medicines can have effect on Skypara suppositories.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- Other medicines that contain acetaminophen – do not take Skypara suppositories at the same time.
- Barbiturates (a type of sedative).
- Medicines for epilepsy or fits (also called ‘anti-convulsants’).
- Medicines such as warfarin for treating blood clots
- Chloramphenicol (a medicine used to treat bacterial infections).
- Probenecid (a medicine used to prevent gout and, occasionally, to increase blood levels of the antibiotic penicillin)

Skypara suppositories with alcohol

Do not take with alcohol, or any medicines containing alcohol, while you are taking these suppositories.

3. How to take SKYPARA -500 suppositories

Always take 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.

Use in Children and adults aged 12 years and above (Body weight: 40 kg and above):

- Skypara suppositories 500 mg are for Children and adults aged from 12 years and above having body weight between 40 kg and above.
- The number of suppositories to be taken depends on your age and weight
- The recommended dose is one to two suppositories
- You should ask your doctor or pharmacist for advice on how many suppositories to take.

You can take up to 4 - 8 doses in 24 hours, dose depending on the body weight. You must leave at least 4 – 6 hours between each dose.

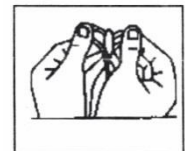
If you are not sure how many suppositories to be taken, don't guess. Ask your doctor or pharmacist for advice.

Do not take more suppositories than stated above.

Contact your doctor if your symptoms get worse or do not improve.

How to inserts the suppositories

- Wash your hands.
- Take out the strip of suppositories and tear off one along the perforation.
- Then take the suppository out of the plastic wrapping by pulling back the loose end.
- Lie on one side with your knees pulled up towards your chest.
- Gently push the suppository pointed end first into your back passage (rectum) with your finger. Push the suppository in as far as possible as shown in the diagram.
- Lower your legs and, if possible, stay still for a few minutes.
- If you feel as if you need to push the suppository out, try to resist this by lying still with your buttocks pressed together. It is important to keep the suppository in the rectum to allow it to melt and the medicine to be absorbed. Pushing the suppository high into the rectum with your finger will help to reduce this feeling.
- Wash your hands.



What if you use too many suppositories?

If high doses are taken pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion.can occur. If you accidentally use too many suppositories or use them too often, tell your doctor or go to your nearest casualty department straight away.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects can happen with this medicine.

Common (may affect up to 1 in 10 people)

- Redness or soreness in or around the back passage.

Rare (may affect up to 1 in 1,000 people)

- Allergic reactions such as swelling of the face, lips, tongue or throat.
- Skin problems such as a rash or itching.
- Blood problems. If these happen, you may bruise or bleed more easily, get infections more easily, or get a high temperature (fever) and ulcers in the mouth and throat.
- Liver problems (you may need to have blood tests to check how well your liver is working).

Very rare cases of serious skin reactions have been reported.

5. How to Store SKYPARA-500 Suppositories

Store below 30⁰ C protected from light. Keep the suppositories in their original pack.

Keep out of the reach of children.

Do not use the suppositories after the expiry date which is printed on the outside of the pack.

If your doctor tells you to stop using them, please take any unused suppositories back to your pharmacist to be destroyed. Do not throw them away with your normal household water or waste. This will help to protect the environment.

6. Further Information

What SKYPARA -500 Suppositories contains;

The active ingredient acetaminophen 1000 mg.

The other ingredient is hard fat.

What SKYPARA-500 Suppositories look like and contents of the pack

SKYPARA-500 is White opaque bullet shaped suppository.

2 Strips of 5 suppositories in polyvinyl chloride/ polyethylene (PVC/PE) foil in monocarton along with insert.

MARKETING AUTHORIZATION HOLDER:

Kremoint Pharma Pvt. Ltd.

D59/60, Additional Ambernath, MIDC, (East), Thane, Ambernath – 421506