

Patient Information Leaflet

Acetaminophen Suppositories USP 125/250 mg (SKYPARA – 125/250 Suppositories)

Read all of this leaflet carefully before you give this medicine to your child because it contains important information for your child.

Always use this medicine exactly as described in this leaflet or as your child's 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 your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your child does not feel better or if your child feels worse.

What is in the leaflet:

1. What SKYPARA – 125/250 suppositories are and what they are used for
2. What you need to know before you give Skypara suppositories to your child.
3. How to give SKYPARA - 125/250 suppositories to your child
4. Possible side effects
5. How to store SKYPARA - 125/250 suppositories
6. Contents of the pack and other information

1. What SKYPARA – 125/250 suppositories are and what they are used for

SKYPARA – 125/250 suppositories contain a medicine called acetaminophen. This belongs to a group of medicines called pain-killers (analgesics).

SKYPARA – 125 Suppositories are used treat pain and high temperature (fever) in children from age 1 to 5 years of age (10 – 20 kg Body weight).

SKYPARA – 250 Suppositories are used treat pain and high temperature (fever) in children from age 5 to 12 years of age (20 – 40 kg Body weight)

They are used by children who find it difficult to take acetaminophen as tablets or syrup.

2. What you need to know before you give Skypara suppositories to your child

Do not give Skypara suppositories to your child:

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

Warnings and Precautions:

Talk to your child's doctor or pharmacist before using these suppositories

- if your child has liver or kidney problems.
- if your child is taking other medicines which can affect their liver.

Other medicines and Skypara suppositories

Tell your child's doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, this includes medicines that you buy without 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 child's doctor or pharmacist if your child is taking any of the following:

- Other medicines that contain acetaminophen – do not give your child 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 give your child alcohol, or any medicines containing alcohol, while they are being given these suppositories.

3. How to give SKYPARA – 125/250 suppositories to your child

Always give this medicine to your child exactly as described in this leaflet or as your child's doctor or pharmacist has told you. Check with your child's doctor or pharmacist if you are not sure.

Use in Children aged 1 to 5 years (10 – 20 kg Body weight):

- Skypara suppositories 125 mg are for children aged from 1 to 5 years.

- The number of suppositories to give your child depends on their age and weight
- The recommended dose is one or two suppositories
- You should ask your child's doctor or pharmacist for advice on how many suppositories to give.

Use in Children aged 5 to 12 years (20 – 40 kg Body weight):

- Skypara suppositories 250 mg are for children aged from 5 to 12 years.
- The number of suppositories to give your child depends on their age and weight
- The recommended dose is one or two suppositories
- You should ask your child's doctor or pharmacist for advice on how many suppositories to give.

You can give your child up to 4 doses in 24 hours. You must leave at least 4 hours between each dose.

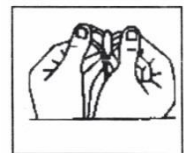
If you are not sure how many suppositories to give your child, don't guess. Ask your child's doctor or pharmacist for advice.

Do not give your child more suppositories than stated above.

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

How to insert 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.



If you give more Skypara suppositories to your child than you should

- Do not give your child more suppositories than stated in leaflet.

- Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage. Your child may need to have a blood test to check how well their liver is working.

If you forgot to give Skypara suppositories to your child

- If you forget to give your child a dose of Skypara suppositories, give it to them as soon as you remember.
- However, if it is almost time for the next dose, skip the missed dose.
- Do not give your child a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your child's doctor or pharmacist.

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, your child 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 (your child may need to have blood tests to check how well their liver is working).

Very rare cases of serious skin reactions have been reported.

5. How to store SKYPARA – 125/250 Suppositories

Store below 30°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-125/250 Suppositories contain?

The active substance is Acetaminophen.

Each SKYPARA-125 suppository contains 125 mg of Acetaminophen USP.

Each SKYPARA -250 suppository contains 250 mg of Acetaminophen USP.

The other ingredients are Polyethylene Glycol -1500 (PEG-1500), Polyethylene Glycol-6000 (PEG-6000), Methyl Paraben, Propyl Paraben, Butylated Hydroxy Toluene, Titanium Dioxide.

What SKYPARA-125/250 Suppositories look like and contents of the pack?

SKYPARA Suppositories are white opaque bullet shaped. All the strengths are having 2 strips of polyvinylchloride foil coated with Polyethylene (PVC-PE) containing 5 suppositories each packed in a carton along with a pack insert.

MARKETING AUTHORIZATION HOLDER:

Kremoint Pharma Pvt. Ltd.

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