

PATIENT INFORMATION LEAFLET

TumsUP Drops

Simethicone, Dill Oil and Fennel Oil Liquid

Read all of this leaflet carefully before your child starts 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.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What **TumsUP Drops** are and what are they used for
2. What you need to know before you take **TumsUP Drops**
3. How to take **TumsUP Drops**
4. Possible side effects
5. How to store **TumsUP Drops**
6. Contents of the pack and other information

1. What TumsUP Drops is and what it is used for

TumsUP Drops contains Simethicone, Dill Oil and Fennel Oil Liquid.

Simethicone belongs to a group of medicines called surface active substances. It works by helping to release trapped wind. This helps to relieve tummy pain and indigestion. Dill oil and fennel oil contains volatile oils that produce smooth muscle relaxation, an antispasmodic effect and increases intestinal motility. Dill and fennel oils are also used for digestion problems including intestinal gas and constipation.

TumsUP Drops are for the gentle relief of wind and griping pains and flatulence in babies.

This medicine can be used from birth onwards.

2. What you need to know before you use TumsUP Drops

Do not give TumsUP Drops if your baby is being treated for a thyroid disorder, seek advice from your doctor instead.

Do not give TumsUP Drops if you think your baby might be allergic (hypersensitive) to Simethicone, Dill Oil and Fennel Oil Liquid.

Taking other medicines

If your baby is being treated with levothyroxine for a thyroid disorder, using TumsUP Drops might reduce the amount of this type of medicine that is absorbed, weakening the effect of their treatment.

3. How to take TumsUP Drops

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

For paediatric use only formulation.

SHAKE WELL BEFORE USE.

Use calibrated dropper provided in this pack.

In infants (below 6 months) 5-10 drops should be given 4 times daily, 15 minutes before feed.

In Infants (6-12 months) 10-20 drops should be given 4 times daily, 15 minutes before feed.

Children (over 1 year) should be given 20 drops 4 times daily, 15 minutes before feed or as directed by the Physician.

Replace cap tightly immediately after each use.

If you use more TumsUP Drops than you should, contact your health advisor for advice.

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.

If you notice any signs of allergy, stop using the product and seek medical advice.

Minor adverse effects: nausea, mild diarrhoea and constipation. Rarely, hypersensitivity reactions such as rash, itching, facial swelling, tongue oedema and respiratory difficulty have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top right end of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

You can also report the side effect with the help of your treating physician.

5. How to store TumsUP Drops

Keep this medicine out of the sight and reach of children.

Store in a cool place. Away from light.

Do not take Tums UP Drops after the expiry date which is stated on the carton. The expiry date refers to the last day of that month after EXP.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What TumsUP Drops contains

Each ml contains:

Simethicone Emulsion equivalent to Simethicone USP..... 40 mg

Dill Oil BP..... 0.005 ml

Fennel Oil..... 0.0007 ml

In syrupy base

Packaging

A bottle of 30 ml

Marketing Authorisation Holder

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