

INSTRUCTIONS FOR USE Montelukast Sodium
MON-te-LOO-kast SO-dee-um
oral granules

This Instructions for Use contains information on how to use montelukast sodium oral granules.

Important Information:

- Before giving a dose of montelukast sodium oral granules, read this Instructions for Use to be sure you prepare and give the oral granules correctly.
- Give montelukast sodium oral granules to your child exactly as instructed by your healthcare provider.
- Stop giving montelukast sodium and tell your healthcare provider right away if your child has any unusual changes in behavior or thinking.
- Continue to give your child their asthma medicines as prescribed, unless your healthcare provider tells you to change how you give these medicines.
- You can give montelukast sodium granules with food or without food.

How can I give montelukast sodium oral granules to my child?

- **Do not** open the packet until ready to use.
- There are different ways you can give montelukast sodium 4-mg oral granules. You should choose the best method for your child:
 - right into the mouth
 - dissolved in 1 teaspoonful (5 mL) of cold or room temperature baby formula or breast milk
 - mixed with 1 spoonful of one of the following soft foods at cold or room temperature: applesauce, mashed carrots, rice, or ice cream.
- Give the child all of the mixture within 15 minutes.
- **Do not store any leftover montelukast sodium mixture (oral granules mixed with food, baby formula, or breast milk) for use at a later time.** Throw away any unused portion.
- **Do not mix montelukast sodium oral granules with any liquid drink other than baby formula or breast milk.** Your child may drink other liquids after swallowing the mixture.

How should I store montelukast sodium?

- Store montelukast sodium at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep montelukast sodium in the package it comes in.
- Keep montelukast sodium in a dry place and keep it away from light.
- **Keep montelukast sodium and all medicines out of the reach of children.**



Manufactured by:
TORRENT PHARMACEUTICALS LTD., INDIA.
Manufactured for:
TORRENT PHARMA INC., Basking Ridge, NJ 07920.

This Instructions for Use has been approved by the U.S. Food and Drug Administration
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