Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Emetostop is and what it is used for
2. Before you take Emetostop
3. How to use Emetostop
4. Possible side effects
5. How to store Emetostop
6. Further information

1. WHAT EMETOSTOP IS AND WHAT IT IS USED FOR

Emetostop belongs to a group of medicines called antihistamines. It blocks the effects of the naturally occurring chemical histamine in your body. It is used to prevent and treat nausea, vomiting, and dizziness caused by motion sickness. It may also be used to reduce lightheadedness, dizziness and loss of balance (vertigo) caused by diseases that affect the inner ear.

2. BEFORE YOU TAKE EMETOSTOP

Do not use Emetostop
- if you are hypersensitive (allergic) to meclozine hydrochloride or any of the other ingredients of Emetostop.
- if you are breast-feeding.

Take special care with Emetostop
- if you suffer from asthma, bronchitis, emphysema, or other lung disease
- if you suffer from glaucoma
- if you have difficulty urinating or an enlarged prostate gland
- if you suffer from severe or chronic constipation

You may require a dosage adjustment or special monitoring during treatment if you have any of the conditions listed above.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The effect of certain medicines may be increased or reduced when used simultaneously with Emetostop. Such medicines include:

Acetylcholinesterase Inhibitors (Central): Anticholinergics may reduce the therapeutic effect of Acetylcholinesterase Inhibitors (Central). Acetylcholinesterase Inhibitors (Central) may reduce the
therapeutic effect of Anticholinergics. If the anticholinergic action is a side effect of the agent, the result may be beneficial.

**Anticholinergics**: May increase the adverse/toxic effect of other Anticholinergics. **Exceptions**: Paliperidone.

**Betahistine**: Antihistamines may reduce the therapeutic effect of Betahistine.

**CNS Depressants**: May increase the adverse/toxic effect of other CNS Depressants.

**Pramlintide**: May increase the anticholinergic effect of Anticholinergics. These effects are specific to the gastrointestinal tract.

**Taking Emetostop with food and drink**
Alcohol should be avoided while taking these tablets since the effects of alcohol may be increased. CNS Depressants may increase the CNS depressant effect of alcohol.

**Pregnancy and breast-feeding**
If you are pregnant or likely to become pregnant, ask your doctor or pharmacist for advice before taking any medicine. Emetostop is contraindicated in lactating women since it is excreted in breast milk.

**Driving and using machines**
Emetostop may cause dizziness, drowsiness or blurred vision. If you are affected, do not drive or operate any tools or machines.

**3. HOW TO USE EMETOSTOP**

Always use Emetostop exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and children over 12 years:
Motion sickness: 1-2 tablets daily. The tablets should be taken 1 hour before you start to travel. Emetostop can remain active for 24 hours after one dose.
Vertigo: 1-4 tablets daily divided in equal doses depending on patient’s response.

These tablets are not intended for children under the age of 12 years.

**If you use more Emetostop than you should**
Contact your doctor immediately or go to the nearest hospital. In overdosage cases, gastric lavage should be performed together with the usual supportive measures. There is no specific antidote.
Symptoms of Emetostop overdose include extreme drowsiness, seizures, hallucinations, and decreased breathing.

**If you forget to take Emetostop**
If you forget to take your medicine, but remember to take it after a short time, take the next tablet normally, when it is the time to take it. However, if a long delay has occurred (e.g. all day) skip the forgotten dose and take the next dose the next day at the usual time. Do not take a double or a larger dose to make up with a forgotten dose (s). Repeated skipping is to be avoided.
4. **POSSIBLE SIDE EFFECTS**

Like all medicines, Emetostop can cause side effects, although not everybody gets them. The following side effects have been reported during treatment:

*Very common side effects (occur in more than 1 in 10 users):*
Central nervous system: Slight to moderate drowsiness
Respiratory: Thickening of bronchial secretions

*Common side effects (occur in between 1 in 100 and 1 in 10 users):*
Central nervous system: Headache, fatigue, nervousness, dizziness
Gastrointestinal: Appetite increase, weight gain, nausea, diarrhoea, abdominal pain, xerostomia
Respiratory: Pharyngitis

*Rare (occur in between 1 in 10000 and 1 in 1000 users):*
Palpitation, hypotension, depression, sedation, photosensitivity, rash, angioedema, urinary retention, hepatitis, myalgia, tremor, paraesthesia, blurred vision, bronchospasm, epistaxis

5. **HOW TO STORE EMETOSTOP**

Keep out of the reach and sight of children.

Store below 25°C.

Do not use Emetostop after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use Emetostop if you notice visible changes in the appearance of the medicinal product.

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

6. **FURTHER INFORMATION**

**What Emetostop contains**
- The active substance is meclozine hydrochloride
- The other ingredients are lactose monohydrate, starch maize, cellulose microcrystalline, polyvidone, quinoline yellow (E104), magnesium stearate, sodium starch glycollate, talc.

**What Emetostop looks like and content of the pack**
Off-yellow, round, biconvex tablets

Contents of container: 10 tablets (in 10-tablets blister packs).

**Marketing Authorisation Holder and Manufacturer**
Specifar S.A.
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