

SMOOD-10 TABLET

Domperidone 10 mg

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What Smood-10 is used for

Smood-10 is used for the relief of the symptoms of nausea and vomiting from various causes (including chemotherapy, radiotherapy or other medicines).

How Smood-10 works

Smood-10 works by blocking the action of a chemical messenger in the brain which causes the feeling of nausea and vomiting, as well as increasing the movement or contractions of the stomach and intestines, allowing food to move more easily through the stomach.

Before your use Smood-10

- When you must not use it

You should not use Smood-10 if:

- You know you are allergic (hypersensitive) to domperidone and other ingredients listed at the end of the leaflet.
- You suffer from a tumour of the pituitary gland called prolactinoma.
- Have bleeding, obstruction and hole in the stomach and bowel (e.g. severe stomach cramps or persistent black stools).
- Have moderate to severe liver disease.
- Have abnormal potassium level, low magnesium level in the blood.
- Have or had heart problems including heart failure or heart rhythm disorders including a slow or irregular heartbeat.

If in doubt, ask your pharmacist or doctor for advice.

Stop taking Smood-10 and contact your doctor immediately if you experience abnormal heartbeat.

Pregnancy

If you are pregnant or think you may be, tell your doctor, who will decide if you can take Smood-10.

Breast-feeding

Small amounts of Smood-10 can end up in the mother's milk. Breast-feeding is not recommended for mothers who are taking Smood-10. Talk to your doctor if you have any questions.

- Before you start to use it

Before taking Smood-10, you should let your doctor know if you have severe kidney problems.

If you are older than 60 years of age, talk to your doctor before taking this medicine.

If you have any of these conditions, talk to your doctor before taking Smood-10.

- Taking other medicines

Always tell your doctor or pharmacists if you are taking any medicines, including those available without a prescription. If in doubt, ask your doctor or pharmacist for advice.

Tell your doctor or pharmacists if you are taking medicine to treat:

- Heart problems (disopyramide, quinidine, amiodarone, defetilide, dronedarone, ibutilide, sotalol).
- Mental illness (haloperidol, pimozide, sertindole).
- Depression (citalopram, escitalopram).
- Bacterial infections (levofloxacin, moxifloxacin).
- Fungal infection (pentamidine).
- Malaria (halofantrine).
- Stomach problems (dolasetron).
- Cancer (toremifene, vendtanib).

- Other illness (bepridil, methadone).

Your doctor will decide if these medicines can be taken together with Smood-10 or if you will need to be monitored closely for heart problem side effects.

Tell your doctor if you are taking anticholinergics (medicines to treat allergy or cough, for example, dextromethorphan or diphenhydramine) as these may affect Smood-10.

Tell your doctor if you are taking medicine(s) for stomach acid. These medicines can be taken if you are also taking Smood-10 but they should not be taken at the same time. You should take oral Smood-10 before meals and the stomach acid medicine after meals.

How to use Smood-10

- How much to use

You should always take the lowest amount of Smood-10 that works for you and you should not take it for longer than is necessary. Although the amount of Smood-10 you should take is described below, your doctor may adjust your dose to your personal needs.

Smood-10 is most effective if taken 15-30 minutes before meals.

Adults and adolescents (12 years of age and over) weighing 35 kg or more; children weighing 35kg or more:

Take 1 tablet, 3-4 times a day. Do not take more than 4 tablets per day (40mg/day).

Infants and children less than 12 years of age and weighing less than 35kg: The effectiveness of Smood-10 has not been established in infants and children under 12 years of age with body weight less than 35kg.

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- When to use it

Smood-10 is most effective if taken 15-30 minutes before meals, and if needed before you go to bed.

- How long to use it

When Smood-10 has not been prescribed for you by a doctor, the following information applies:

If Smood-10 is used for short term nausea and vomiting, you should not usually need to take it for more than one week. Talk to your doctor if your nausea and vomiting lasts for more than one week.

For other indications, the initial duration of treatment is up to four weeks.

- If you forget to use it

Take your dose as soon as you remember, and then continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

- If you use too much (overdose)

Overdose has been reported primarily in infants and children. If you have taken too much Smood-10 you may experience agitation, altered state of awareness, seizure, confusion, sleepiness, uncontrolled movements.

See your doctor, especially if a child has taken the medicine.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Smood-10.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Smood-10 to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Do not drive or operate machines if you feel tired, sleepy or dizzy after taking your medicine.

Side effects

You may experience unwanted effects when using Smood-10. Listed below are side effects (also called adverse reactions) related to treatment with Smood-10:

Very rare (reported by fewer than 1 in 10000 people):

- Severe allergic reaction that may include:
 - A swollen face, lips, mouth, tongue or throat
 - Difficulty swallowing or breathing
 - Itchy rashes (hives)
- Abnormal heart rhythm
- Unexpected death resulting from an abrupt loss of heart function in a person who may or may not have known heart disease.

Stop taking Smood-10 and contact your doctor immediately if you experience any of the unwanted events described above.

Other unwanted effects that have been observed with Smood-10 are listed below:

Common (reported by at least 1 in 100 people but fewer than 1 in 10 people):

- Depression
- Anxiety
- Loss or diminished interest in sex
- Headache
- Sleepiness
- Restlessness
- Diarrhea
- Rash
- Itchiness
- Painful or tender breasts
- Milk discharge from breasts or difficulty breast feeding
- Irregular menstrual periods in women
- A general feeling of weakness

Uncommon (reported by at least 1 in 1000 people but fewer than 1 in 100 people):

- Hypersensitivity
- Hives
- Unusual discharge from breasts
- Swollen breasts

If your child experience any of these effects, stop taking Smood-10 and consult your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Smood-10

- Storage

Keep out of children.
Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

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These measures will help to protect the environment.

Product description

- What it looks like

Round, 6.0 mm in diameter, white to off-white coated tablet with shallow convex faces.

- Ingredients

- Active ingredients

Each tablet contains Domperidone Maleate equivalent to Domperidone 20 mg.

- Inactive ingredients

Pregelatinised starch
Microcrystalline cellulose
Sodium starch glycolate
Colloidal silicon dioxide
Talc
Magnesium stearate
HPMC E-5
HPMC E-15
Titanium dioxide
Propylene glycol

- MAL Number

MAL12070005AZ

Manufacturer

HOVID Berhad
Lot 56442, 7 ½ Miles, Jalan Ipoh/
Chemor, 31200 Chemor, Perak,
Malaysia.

Product Registration Holder

HOVID Berhad
121, Jalan Tunku Abdul Rahman
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Perak, Malaysia.

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