READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

DIMENHYDRINATE INJECTION USP

For IM administration or IV administration if diluted
50 mg/mL

For IV administration
10 mg/mL

SANDOZ DIMENHYDRINATE

Dimenhydrinate suppositories
50 mg and 100 mg

Read this carefully before you start taking Dimenhydrinate Injection USP or Sandoz Dimenhydrinate and each time you get a refill. This leaflet is a summary and will not tell you everything about these drugs. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Dimenhydrinate Injection USP or Sandoz Dimenhydrinate.

What are Dimenhydrinate Injection USP and Sandoz Dimenhydrinate used for?
Dimenhydrinate Injection USP and Sandoz Dimenhydrinate are used to prevent and relieve symptoms such as:
- Nausea
- vomiting and/or
- vertigo

These symptoms may be the result of:
- motion sickness
- radiation sickness
- postoperative recovery
- taking other drugs
- an ear condition (Menière’s disease and other labyrinthine disturbances)

How do Dimenhydrinate Injection USP and Sandoz Dimenhydrinate work?
Dimenhydrinate Injection USP and Sandoz Dimenhydrinate belong to a family of drugs called antiemetics. It works by:
- affecting the brain and inner ear to help prevent problems with the body’s balance
- blocking processes that are involved in the vomiting reflex
What are the ingredients in Dimenhydrinate Injection USP and Sandoz Dimenhydrinate?
Medicinal ingredient: dimenhydrinate

Non-medicinal ingredients:

Dimenhydrinate Injection USP For IM administration or IV administration if diluted 50 mg/mL Ampoules  propylene glycol 50% and water for injection.

Dimenhydrinate Injection USP For IM administration or IV administration if diluted 50 mg/mL Multidose vials  benzyl alcohol 5%, propylene glycol 50% and water for injection.

Dimenhydrinate Injection USP For IV administration 10 mg/mL Single vials  ethyl alcohol 10% and water for injection.

Sandoz Dimenhydrinate Suppositories 50 mg  hard fat.

Sandoz Dimenhydrinate Suppositories 100 mg  hard fat.

Dimenhydrinate Injection USP comes in the following dosage form:
- Solution for injection: 50 mg/mL and 10 mg/mL

Sandoz Dimenhydrinate comes in the following dosage form:
- Suppositories: 50 mg and 100 mg

Do not use Dimenhydrinate Injection USP or Sandoz Dimenhydrinate if you:
- are allergic to dimenhydrinate or any of the other ingredients in Dimenhydrinate Injection USP and Sandoz Dimenhydrinate (see What are the ingredients in Dimenhydrinate Injection USP and Sandoz Dimenhydrinate)
- take a Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid and methylene blue. Do not:
  - Take an MAOI within 2 weeks of stopping Dimenhydrinate Injection USP and Sandoz Dimenhydrinate unless told to do so by your doctor
  - Start Dimenhydrinate Injection USP and Sandoz Dimenhydrinate if you stopped taking an MAOI in the last 2 weeks unless told to do so by your doctor
- Have glaucoma
- Have chronic lung disease including:
  - asthma
  - chronic obstructive pulmonary disease
lower respiratory tract symptoms

- Have difficulty urinating due to an enlarged prostate
- Are 6 years old or younger for Dimenhydrinate Injection USP
- Are 12 years old or younger for Sandoz Dimenhydrinate

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Dimenhydrinate Injection USP or Sandoz Dimenhydrinate. Talk about any health conditions or problems you may have, including if you:

- have a history of heart problems, including high blood pressure
- have a history of seizures
- have problems with your thyroid
- have or had liver problems
- are pregnant or planning to become pregnant
- are breastfeeding or planning to breastfeed
- have porphyria (a condition that affects your hemoglobin)

Other warnings you should know about:
Do not take more than the recommended dose. At high doses, Dimenhydrinate Injection USP and Sandoz Dimenhydrinate can cause:

- confusion
- hallucinations
- temporary amnesia
- paranoia

Abuse: chronic abuse of Dimenhydrinate Injection USP or Sandoz Dimenhydrinate can lead to accidents, overdose, and in extreme cases to death. Dimenhydrinate Injection USP or Sandoz Dimenhydrinate should not be used for prolonged periods except on the advice of your doctor.

Driving and using machines: Before doing tasks that require special attention, wait until you know how you respond to Dimenhydrinate Injection USP or Sandoz Dimenhydrinate.

Pregnancy: Do not take Dimenhydrinate Injection USP or Sandoz Dimenhydrinate for nausea or vomiting while pregnant unless told to do so by your doctor.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Dimenhydrinate Injection USP or Sandoz Dimenhydrinate:

- Alcohol
- Some drugs used to treat depression (MAO inhibitors)
- Drugs used to help you sleep such as:
  - barbiturates
  - sedatives
  - hypnotics
- Drugs used to reduce tension or anxiety (such as tranquilizers)

To avoid an overdose, you should use caution when taking Dimenhydrinate Injection USP or Sandoz Dimenhydrinate with these types of drugs.
- Drugs used to treat allergies or allergic reactions (antihistamines)
- Drugs that can cause damage to the ear (called ototoxic drugs). If you take dimenhydrinate in combination with certain antibiotics or other drugs that can cause damage to the ear, you may not be able to see the early symptoms of ototoxicity.

**How to take Dimenhydrinate Injection USP and Sandoz Dimenhydrinate:**

**Dimenhydrinate Injection USP for IM administration is for intramuscular use only.**

**If used for intravenous (IV) administration,** Dimenhydrinate Injection USP 50 mg/mL must be diluted at least one to ten with a compatible physiological solution (such as sterile saline or 5% dextrose and water). Diluted Dimenhydrinate Injection USP for IM administration, prepared for IV use, should be administered by SLOW INTRAVENOUS INJECTION ONLY (over 2 minutes).

For IV administration, the Dimenhydrinate Injection USP (10 mg/mL) must be administered as a slow IV injection (2 to 4 minutes).

**For Motion Sickness**

**Adults**

**Rectal:**
**Usual dose:** 50 mg - 100 mg Sandoz Dimenhydrinate suppository every 6 to 8 hours as needed.
For ease and comfort, smooth any edges on suppository prior to use.
Dosage should be taken at least 30 minutes, and preferably 1 or 2 hours before travelling. Do not use more than 4 suppositories in 24 hours.

**Children**

**12 years of age and older:**

**Rectal:**
**Usual dose:** 50 mg every 8 to 12 hours as needed. Dosage should be taken at least 30 minutes, and preferably 1 or 2 hours before travelling. Do not use more than 3 suppositories in 24 hours.

**For Radiation Sickness**

**Pre-Therapy:**
**Usual adult dose:** 50 mg – 100 mg given rectally or by injection, 30 to 60 minutes before treatment
**Maximum daily dose:** This dose can be given again up to 400 mg a day
To divide a suppository in two equal parts, remove from packaging and carefully cut with a sharp edge blade through the suppository.

Post-therapy:
Usual adult dose: 50 mg given IM or by IV 1.5 hours after therapy and 50 given mg IM or by IV 3 hours - after therapy

Postoperative Nausea/Vomiting

Adults
Usual pre-operative dose: 50 mg IM or by IV
Usual post-operative dose: 50 mg IM or by IV
Maximum daily dose: 400 mg a day

Children
Usual dose for Over 12 years of age: 50 mg given IM or by IV 2 or 3 times a day
Usual dose for 8 to 12 years of age: 25 mg - 50 mg given IM or by IV 2 or 3 times a day
Usual dose for 6 to 7 years of age: 15 mg - 25 mg given IM or by IV 2 or 3 times a day

Post-surgical/Post-anesthetic

Adults:
Usual dose: 50 mg given IM or by IV immediately after surgery. Then 50 mg given IM or by IV every 4 hours for 3 doses

Children:
Usual dose for Over 12 years of age: 50 mg given IM or by IV 2 or 3 times a day
Usual dose for 8 to 12 years of age: 25 mg - 50 mg given IM or by IV 2 or 3 times a day
Usual dose for 6 to 7 years of age: 15 mg - 25 mg given IM or by IV 2 or 3 times a day

Overdose:
If you think you have taken too much Dimenhydrinate Injection USP or Sandoz Dimenhydrinate, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you miss a dose and you are taking it regularly, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once. Do not exceed the maximum daily dose.

What are possible side effects from using Dimenhydrinate Injection USP or Sandoz Dimenhydrinate?
These are not all the possible side effects you may feel when taking Dimenhydrinate Injection USP or Sandoz Dimenhydrinate. If you experience any side effects not listed here, contact your healthcare professional.

- drowsiness
- dizziness
- pain may occur at the site of IM injection
- dry mouth
- fatigue, excitement
- nausea

**Skin Rash:** If you experience a skin rash after taking Dimenhydrinate Injection USP or Sandoz Dimenhydrinate, you should contact your doctor or pharmacist for assessment and advice.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Reporting Side Effects**
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting [https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**
Dimenhydrinate Injection USP solutions should be stored at controlled room temperature (15°C – 30°C). Protect from freezing. Protect from light.

Sandoz Dimenhydrinate (suppositories) should be stored below 25°C.

Keep out of reach and sight of children.

If you want more information about Dimenhydrinate Injection USP and Sandoz Dimenhydrinate:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website ([https://health-products.canada.ca/dpd-bdpp/index-eng.jsp](https://health-products.canada.ca/dpd-bdpp/index-eng.jsp)); the manufacturer's website [www.sandoz.ca](http://www.sandoz.ca), or by calling 1-800-361-3062.

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