

HEPTRAL® 500MG GASTRORESISTANT TABLETS

Ademetionine 1,4-butanedisulfonate (500mg)

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What Heptral® is used for

Heptral® is used to treat cholestasis (a type of liver disease) in pregnant and non-pregnant individuals. It is also used to relief tiredness caused by chronic liver disease.

How Heptral® works

Heptral® contains amino acid called S-adenosyl-L-methionine (ademetionine). It acts as a coenzyme to maintain and restore metabolic processes in the liver and produce antioxidants (glutathione) that help in liver detoxification.

Before you use Heptral®

- When you must not use it

Do not take Heptral® if:

- You are allergic (hypersensitive) to ademetionine or any of the other ingredients of Heptral®
- You have genetic defects affecting the methionine cycle (a pathway that is essential in growth and development).

Do not use Heptral® if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Heptral®.

- Before you start to use it

Talk to your doctor or pharmacist before taking Heptral® if you suffer from any medical conditions or illnesses, in particular:

- if you have bipolar disease (a type of mental disorder) or anxiety
- if you have liver or kidney problem
- if you are anemic or vegetarian
- if you are pregnant, or could be pregnant

If any of the above applies to you, your doctor will tell you whether it is safe for you to start taking Heptral®.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular:

- tricyclic antidepressants (eg. Clomipramine), used in treating psychological disorder
- selective serotonin reuptake inhibitors (SSRI) used in treating psychological disorder
- supplements that contain tryptophan

How to use Heptral®

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dosing is 10-25 mg/kg/day. The usual starting dose is 400-800 mg/day, total daily dose not to exceed 1600mg.

Maintenance therapy:
800 to 1600 mg/day

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Heptral® for as long as your doctor or pharmacist recommends.

- If you forget to use it

Do not take a double dose to make up for the forgotten dose. Take the next dose at your regular time on the next day. If you are worried about this, talk to your doctor or pharmacist.

- If you use too much (overdose)

If you take more Heptral® than you should stop taking Heptral® and talk to a doctor or pharmacist.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.

No adverse reactions were observed in women in the last three months of pregnancy. It is advisable to administer ademetionine in the first three months of pregnancy or while breast-feeding only if it is absolutely necessary.

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- Things to be careful of

Some people may experience dizziness with the use of ademetionine. It is not advisable to drive during treatment until it is certain that ademetionine therapy does not affect the ability to drive.

Side effects

Like all medicines, Heptral® can cause side effects, although not everybody gets them.

Common (may affect more than 1 in 100 people):

Diarrhoea, abdominal pain, nausea

Uncommon (may affect up to 1 in 100 people)

Dry mouth, indigestion, flatulence, blood in stool, vomiting

Rare (may affect more than 1 in 10000 people)

Abdominal swelling

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

Storage and Disposal of Heptral®

- Storage

Keep this medicine out of the sight and reach of children. Do not use Heptral® after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Heptral® is white to yellowish oval tablet.

Heptral® is available in carton of 10s and 20s tablets.

- Ingredients

- Active ingredient(s)
Ademetionine

- Inactive ingredients
Colloidal anhydrous silica, microcrystalline cellulose, sodium starch glycolate (Type A), magnesium stearate, methacrylic acid - ethyl acrylate copolymer, macrogol 6000, polysorbate 80, simethicone emulsion, sodium hydroxide, talc

- MAL number:

Heptral® 500mg Gastroresistant Tablets:
MAL12020028XC

Manufacturer

Abbvie S.R.L,
S.R. 148 Pontina Km 52 Snc
Campoverde Di Aprilia
04011 Aprilia, Italy

Product Registration Holder

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