

ZYMON MR TABLETS 150MG

Bupropion Hydrochloride Modified Release Tablets 150mg

What is in this leaflet

1. What is Zymon MR Tablets used for
2. How Zymon MR Tablets works
3. Before you use Zymon MR Tablets
4. How to use Zymon MR Tablets
5. While you are using it
6. Side effects
7. Storage and Disposal of Zymon MR Tablets
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What Zymon MR Tablets is used for

Zymon MR Tablets is indicated for the treatment of major depressive episodes.

Ask your doctor if you have any questions about why Zymon MR Tablets been prescribed for you. Your doctor may have prescribed it for another reason.

How Zymon MR Tablets works

Zymon MR Tablets is in a class of medications called antidepressants. It works by increasing certain types of activity in the brain.

Use in Children

Zymon MR Tablets is not indicated for use in children or adolescents under 18 years of age as the safety and efficacy for this age group have not been established.

Before you use Zymon MR Tablets

- When you must not use it

Do not take Zymon MR Tablets:

- If you are allergic to bupropion or any of the other ingredients of this medicine.

Symptoms of an allergic reaction include:

- Skin rash
- Itching or hives on the skin
- Swelling of the face, lips, tongue, throat or other parts of the body
- Hoarseness

- Difficulty breathing or swallowing.
- If you are taking any other medicines which contain bupropion.
- If you are taking, other medications for depression known as monoamine oxidase inhibitors, even if you have stopped taking them, but have taken them within the last 14 days.
- If you have a condition that causes fits (seizures), such as epilepsy, or if you have a history of fits.
- If you have a brain tumor
- If you have severe liver problems, such as cirrhosis (a condition in which your liver is scarred and permanently damaged).
- If you have an eating disorder or had one in the past [for example, bulimia (serious illness that causes severe problems with a person's eating behaviors. It is marked by uncontrolled episodes of overeating, called bingeing) or anorexia nervosa (eating disorder characterized by food restriction, body image disturbance, fear of gaining weight, and an overpowering desire to be thin)].
- If you are an alcohol drinker and undergoing abrupt withdrawal from alcohol or any medicinal product known to be associated with a risk of seizures on withdrawal (in particular benzodiazepines and benzodiazepine-like agents).

Pregnancy and lactation

Zymon MR Tablets should not be used during pregnancy unless the clinical condition of the woman requires treatment with bupropion and alternative treatments are not an option.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed. Bupropion and its metabolites are excreted in human breast milk. A decision on whether to abstain from breast-feeding or to abstain from therapy with Zymon MR Tablets should be made taking into account the benefit of breast-feeding to the newborn/infant and the benefit of

Zymon MR Tablets therapy to the mother.

- Before you start use it

The recommended dose of Zymon MR Tablets should not be exceeded, since bupropion is associated with a dose-related risk of seizure.

There is an increased risk of seizures occurring with the use of Zymon MR Tablets in the presence of predisposing risk factors that lower the seizure threshold.

Zymon MR Tablets should be discontinued and not recommended in patients who experience a seizure while on treatment.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- A current seizure disorder or any history of seizure.
- A personal history or family
- History of bipolar disorder
- Blood pressure problems
- Heart attack
- Head of injury
- A tumor in brain and spine
- Any other medical conditions.
- liver or kidney problems
- Brugada syndrome (a rare hereditary syndrome that affects the heart rhythm).

- Taking other medicines

Tell your doctor or pharmacist if you take any other medicines, including:

- All prescription medicines.
- All of the prescription and non-prescription (over the counter) medicines you are taking as well as any product such as vitamins mineral or other dietary supplement.

Do not start to take any other medicine while you are taking Zymon MR Tablets, unless it is prescribed or approved by your doctor.

Zymon MR Tablets is contraindicated for use in patients with severe hepatic cirrhosis (the irreversible scarring of the liver that occurs from prolonged damage, replacing healthy liver tissue with fibrous scar tissue).

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Concomitant use of Zymon MR Tablets and Monoamine Oxidase Inhibitors (MAOIs) (a type of antidepressant) is contraindicated. At least 14 days should elapse between discontinuation of irreversible MAOIs and initiation of treatment with Zymon MR Tablets. For reversible MAOIs a 24-hour period is sufficient.

Some medicines may interfere with Zymon MR Tablets or Zymon MR Tablets may interfere with these medicines. These include:

- Medications for depression known as certain antidepressants such as desipramine, imipramine.
- Antipsychotics (e.g. risperidone, thioridazine).
- Beta-blockers (a type of medication that helps manage various heart-related conditions e.g. metoprolol)
- Serotonin selective reuptake inhibitors (SSRIs) (class of medications commonly used to treat depression and some other mental health conditions).
- Type 1C antiarrhythmics (medicine used to treat abnormal heart rhythms e.g. propafenone, flecainide).

In these cases, the expected benefit of treatment with Zymon MR Tablets should be carefully compared with the potential risks.

Ask your doctor or pharmacist if you are unsure if you are taking any of these medicines. It is important that you do not take Zymon MR Tablets or medicines similar to Zymon MR Tablets.

Zymon MR Tablets is extensively metabolised caution is advised when Zymon MR Tablets is co-administered with medicinal products known to induce metabolism (e.g. carbamazepine, phenytoin, ritonavir, efavirenz or inhibit metabolism (e.g. valproate), as these may affect its clinical efficacy and safety.

Concomitant use of Zymon MR Tablets and a nicotine patch may result in elevations of blood pressure.

You may need to take different amounts of your medicine, or you may

need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Zymon MR Tablets.

How to use Zymon MR Tablets

- How much to use

The usual dose is 150mg taken once a day with or without food.

Do not change your dose unless your doctor tells you to.

Your doctor will gradually increase your dose if needed.

Zymon MR Tablets is for oral use only. Inhalation of crushed tablets or injection of dissolved bupropion has been reported and may result in rapid release, faster absorption, and possible overdose. Seizures and/or death have been reported when bupropion was administered intranasal or by parenteral injection.

- When to use it

Zymon MR Tablets should be swallowed whole. The tablets should not be cut, crushed or chewed as this may lead to an increased risk of adverse effects including seizures.

Zymon MR Tablets can be taken with or without food

- How long to use it

Continue taking your medicine for as long as your doctor tells you.

Patients with depression should be treated for a sufficient period of at least 6 months to ensure that they are free from symptoms.

This medicine helps to control your condition, so it is important to keep taking your medicine even if you feel well.

- If you forget to use it

Consult your doctor or pharmacist about what to do if you forget to use this medicine.

Take the missed dose as soon as you remember. If it is almost time for the next dose, ignore the missed dose and then continue taking the medication according to the schedule as usual. Do not take a double dose to replace the missed dose.

- If you use too much (overdose)

Contact your doctor or your nearest hospital emergency department immediately if you take too many tablets. The symptoms of overdoses such as:

- Drowsiness.
- Loss of consciousness.
- Arrhythmias (condition where the heart beats irregularly — it can be too fast, too slow, or with an uneven rhythm)
- Tachycardias (is a condition where the heart beats **faster than normal**).

While you are using it

- Things you must do

- Visit your doctor regularly for a check-up so that your progress can be checked. Always discuss any questions you have about Zymon MR Tablets with your doctor.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking Zymon MR Tablets.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking your medicine unless your doctor tells you to.
- Do not take any new medicines without consulting your doctor.
- Do not give Zymon MR to anyone else, even if they have the same symptoms or condition as you.

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- Things to be careful

Driving or operate machinery:

Zymon MR Tablets may affect ability to perform tasks that require judgement, motor and cognitive skill. Patients should therefore exercise caution before driving or use of machinery until they are reasonably certain Zymon MR Tablets does not adversely affect their performance.

Consuming Alcohol

Do not drink a lot of alcohol while taking Zymon MR Tablets. If you usually drink a lot of alcohol, talk with your doctor before suddenly stopping. If you suddenly stop drinking alcohol, you may increase your risk of having seizures.

Worsening of Depression

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Watch carefully for signs that your depression is getting worse, especially in the first few weeks of treatment or if your dose has changed.

Sometimes people with depression can experience a worsening of their depressive symptoms. This can happen even when taking an antidepressant.

Tell your doctor immediately if you experience any of the following symptoms:

- Anorexia (eating disorder characterized by food restriction, body image disturbance, fear of gaining weight, and an overpowering desire to be thin).
- Dry mouth
- Rash
- Sweating
- Tinnitus (when you hear sounds like ringing, buzzing, or hissing in your ears when there's no actual external noise).
- Tremor

Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself.

Suicidality in Children and Adolescents

- Antidepressants increase the risk of suicidal thinking and behavior

(suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.

- Anyone considering the use of an antidepressant in a child or adolescent for any clinical use must balance the risk of increased suicidality with the clinical need.
- Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.
- Families and caregivers should be advised to closely observe the patient and to communicate with the prescriber.
- The indication(s) approved in children and adolescents for the drug should be clearly stated / included.

Side effects

Like all medicines, Zymon MR Tablets can cause side effects, although not everybody gets them.

Common side effects could be:

- Anorexia (eating disorder characterized by food restriction, body image disturbance, fear of gaining weight, and an overpowering desire to be thin).
- Headache.
- Dry mouth.
- Abdominal pain.
- Constipation.
- Increase blood pressure.
- Rash.
- Visual disturbance.
- Fever.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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 Zymon MR Tablets

- Storage

Store below 30°C.

Keep out of the reach and sight of children.

Do not take this medicine after the expiry date (EXP) printed on the pack, or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

- Disposal

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.

Product Description

- What it looks like

White to pale yellow, round, biconvex tablets plain on both sides.

- Ingredients

Active ingredient:

- Bupropion Hydrochloride

Inactive ingredients:

- Povidone (Kollidon®90F)
- Hydrochloric acid (37%-EMPROVE® Exp)
- Ethyl Alcohol Anhydrous
- Sodium Stearyl Fumarate (Pruv®)
- Ethylcellulose (Ethocel N 10 Premium)
- Hydroxy Propylcellulose (Klucel-LF)
- Methacrylic acid-Ethyl Acrylate copolymer (1:1) Type A (Eudragit(R)-L-100 55)
- Silica, Colloidal Anhydrous (Syloid AL 1 FP)
- Macrogols 1500 (POLYGLYKOL 1500 S)
- Triethyl Citrate
- Isopropyl Alcohol
- Purified water
- Opadry Clear YS -1-7006

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- MAL number:

MAL26026006AZ

Manufacturer

Alembic Pharmaceuticals Limited
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Product Registration Holder

GENPHARMA SDN. BHD.
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