MAPRESS TABLET

Haloperidol (0.5mg, 1.5mg, 5mg)

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What MAPRESS is used for

MAPRESS is used to treat mental illnesses such as:

- schizophrenia (an illness with disturbances in thinking, feelings and behaviour)
- psychosis due to organic brain damage or mental deficiency
- senile psychosis (mental disturbance of old age)
- mania
- Gilles de Tourette syndrome (a condition that causes a person to make repeated, quick movements or sounds that they cannot control)
- delusions, hallucinations, confusions, tremor and aggression
- nausea and vomiting (caused by cancer treatment)

How MAPRESS works

MAPRESS contains the active ingredient, haloperidol. Haloperidol belongs to a group of medicines called antipsychotics. It helps to correct chemical imbalances in the brain, which may cause mental illness. It blocks the transmission in the brain.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

MAPRESS is only available with a doctor's prescription.

Before you use MAPRESS

When you must not use it

Do not take MAPRESS if you have an allergy to:

- haloperidol
- any of the other ingredients of MAPRESS listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

Do not take MAPRESS if you have, or have had, any of the following conditions:

- Brain damage
- Comatose states
- Depression (due to alcohol and other depressant drug)
- Parkinson's disease

If you are not sure whether any of the above conditions apply to you, ask your doctor.

MAPRESS is not recommended for use in children under 3 years of age.

Do not take this medicine after the expiry date 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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- heart and blood vessel problems
- liver disease
- epilepsy
- thyrotoxicosis (an excess of thyroid hormone in the body)

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. It is not recommended for use during pregnancy and breastfeeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking MAPRESS.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and MAPRESS may interfere with each other.

MAPRESS.

These include:

- pain killers
- benzodiazepines
- anticonvulsants, medicines used to control epilepsy
- medicines used to control depression
- antipsychotic medicines, used to treat mental illnesses
- medicines used to treat high blood pressure and heart conditions
- medicines used to treat Parkinson's Disease
- adrenaline, a medicine used in emergency situations
- anticoagulants (to reduce the risk of blood clots)

These medicines may be affected by MAPRESS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use MAPRESS

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to use it

Your doctor will tell you how much MAPRESS you need to take each day. This may depend on your age, your medical condition and whether or not you are taking other medicines.

Adult
Moderate symptomatology:
1 to 5mg per day

Severe symptomatology:

5 to 15mg per day, up to 100mg per day.

Geriatric and debilitated patients
1 to 3mg per day

Children

Initial dose: 1-3 mg per day. Maintenance dose: 0.05 mg per kg of body weight daily.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

Follow the instructions they give you. If you take the wrong dose, MAPRESS may not work as well and your problem may not improve.

When to use it

Take your MAPRESS at the same time each day.

Taking it at the same time each day will have the best effect. It will also help you to remember when to take it.

How long to use it

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

MAPRESS helps to control your condition. Therefore, you must take it every day.

Do not stop taking MAPRESS or lower the dose without first checking with your doctor.

If you forget to use it

Take your dose as soon as you remember, and 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 that you missed. This may increase the chance of you getting an unwanted side effect. If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (overdose) Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Some of the symptoms of an overdose may include hypotension (low blood pressure), blurred vision, disorientation, sedation, muscular weakness or rigidity and tremor, difficulty breathing, fast and irregular heartbeat.

While you are using it

Things you must do

Always follow your doctor's instructions carefully.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MAPRESS.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor immediately if you notice any uncontrolled movements of the tongue, mouth, cheeks, or jaw, which may progress to the arms and legs.

These are symptoms of a condition called tardive dyskinesia, which may develop in people taking antipsychotic medicines, including MAPRESS.

This condition is more likely to occur during long term treatment with this medicine, especially in elderly women.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking MAPRESS.

Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking MAPRESS suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase.

Do not take any medicines that cause drowsiness while you are taking MAPRESS, unless recommended by your doctor.

Do not take MAPRESS to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful when driving or operating machinery until you know how MAPRESS affects you.

As with other antipsychotic medicines, MAPRESS may cause dizziness, light-headedness, tiredness, and drowsiness in some people.

Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

If MAPRESS makes you feel light-headed, dizzy or faint, get up slowly when getting up from a sitting or lying position.

Standing up slowly, especially when you get up from bed or

chairs, will help your body get used to the change in position and blood pressure.

Be careful when drinking alcohol while taking MAPRESS.

Combining MAPRESS and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest to avoid alcohol while you are being treated with MAPRESS.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MAPRESS. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- drowsiness or tiredness
- confusion
- headaches
- inability to sleep
- muscle weakness
- difficulty in speaking and/or swallowing
- dry mouth
- indigestion
- nausea and/or vomiting
- constipation
- blurred vision or difficulty focusing
- swelling of your hands, feet and/or ankles

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of MAPRESS

<u>Storage</u>

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep them in a cool, dry place where the temperature stays below 25°C. Protect from light.

Do not store MAPRESS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Medicines should not be disposed of via wastewater or household waste. Those measures will help to protect the environment.

Product Description

What it looks like

MAPRESS Tablet 0.5mg is a 7mm round tablet, apple green in colour with 'Star' and 'd' markings.

MAPRESS Tablet 1.5mg is a 7mm round tablet, blue in colour with 'Star' and 'd' markings.

MAPRESS Tablet 5mg is a 7mm round tablet, yellow in colour with 'Star' and 'd' markings.

Ingredients

Active ingredient:

• haloperidol

Inactive ingredients:

MAPRESS Tablet 0.5mg

- aerosil
- quinolline yellow
- cornstarch
- polyvinylpyrrolidone
- magnesium stearate
- promigel
- brilliant blue
- lactose

MAPRESS Tablet 1.5mg

- aerosil
- cornstarch
- polyvinylpyrrolidone
- magnesium stearate
- promigel
- brilliant blue
- lactose

MAPRESS Tablet 5mg

- aerosil
- cornstarch
- polyvinylpyrrolidone
- magnesium stearate
- promigel
- quinolline yellow
- lactose

MAL numbers

MAPRESS Tablet 0.5mg MAL19950598A

MAPRESS Tablet 1.5mg MAL19950599A

MAPRESS Tablet 5mg MAL19950600A

Manufacturer

DUOPHARMA (M) SDN BHD Lot 2599, Jalan Seruling 59, Kaw 3, Taman Klang Jaya, 41200 Klang, Selangor, Malaysia.

Product Registration Holder

DUOPHARMA (M) SDN BHD Lot 2599, Jalan Seruling 59, Kaw 3, Taman Klang Jaya, 41200 Klang, Selangor, Malaysia.

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