

ASEPTONE SYRUP

Methadone hydrochloride (5mg/ml)

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What ASEPTONE SYRUP is used for

This medicine is for treatment of addiction in opioid drugs.

ASEPTONE SYRUP is only available with a doctor's prescription.

How ASEPTONE SYRUP works

ASEPTONE SYRUP contains methadone hydrochloride as the active ingredient. It belongs to a group of medicines called opioid.

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.

Before you use ASEPTONE SYRUP

- When you must not use it

Do not take this medicine if you have an allergy to:

- methadone
- any other opioid drugs

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

Symptoms of an allergic reaction may include

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

Do not take ASEPTONE SYRUP if you

- suffer from a lung disorder such as asthma or any illness causing difficulty in breathing
- have a recent head injury or increased pressure in the head
- have a bowel condition known as ulcerative colitis
- have severe liver problem
- alcoholism
- are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs),
- paralytic ileus (paralysis of the intestinal muscle)

If any of these apply to you, get advice from a doctor or pharmacist.

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 of the following medical conditions:

- underactive thyroid gland
- prostate problem
- anxiety
- drug dependence
- hypotensive effect (low blood pressure)
- elderly or debilitated
- hormonal problem
- urethral stricture (narrowing of the urinary tract)
- kidney problem

Please consult your doctor before start to use ASEPTONE syrup if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking ASEPTONE syrup against the benefits they expect it will have for you.

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

ASEPTONE SYRUP contains sodium saccharin as sweetening agent. Phenylketonurics (disorder that causes an amino acid build up in your body) are warned that this product, in some forms, contains phenylalanine.

- 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 ASEPTONE SYRUP may interfere with each other.

These include:

- other Central Nervous System Depressants such as, other narcotic analgesics, phenothiazines, other tranquilizers, sedative-hypnotics, tricyclic antidepressants, and alcohol.
- Pentazocine, narcotic pain reliever
- Rifampin, medicine for infection
- Monoamine Oxidase (MAO) Inhibitors, medicines for depression
- Meperidine, narcotic pain reliever
- Naloxone, medicine for narcotic overdose
- Naltrexone, medicine for opioid addiction
- Antiviral, medicines used for HIV
- Narcotic antagonist, medicines to inhibit the effect of narcotic

These medicines may be affected by ASEPTONE SYRUP 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 ASEPTONE

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

For detoxification treatment:
The initial dose is 15 to 20mg daily.

This dosage may be adjusted by your doctor depending on your condition.

Do not take more than the recommended dose.

ASEPTONE SYRUP is not recommended for use in children.

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

- When to use it

Take ASEPTONE SYRUP as prescribed by your doctor.

It shall be taken daily under close supervision.

- How long to use it

Do not stop taking this medicine or change the dose without first checking with your doctor.

Your doctor may want to gradually reduce the amount you are taking before stopping completely in order to lessen the chance of possible withdrawal side effects.

- If you forget to use it

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

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 ASEPTONE SYRUP.

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

You may need urgent medical attention.

Some of symptoms of overdose include:

- difficulty in breathing
- somnolence (sleepiness) progressing to coma
- constricted pupils
- skeletal muscle flaccidity (lack of muscle tone)
- cold and clammy skin
- bradycardia (reduce heart rate)
- hypotension (low blood pressure)
- apnea (breathing problem)
- circulatory collapse
- heart arrest
- death

While you are using it

- Things you must do

Always follow your doctor's instructions carefully.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

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

- Things you must not do

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

Do not take ASEPTONE SYRUP 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 driving or operating machinery until you know how ASEPTONE SYRUP affects you.

This medicine may cause orthostatic hypotension (low blood pressure due to changing of posture).

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness may be worse.

Particular care should be taken when starting this medicine or increasing the dose. Methadone can decrease heart and breathing rates, which if severe, may lead to death.

Side effects

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:

- respiratory depression
- circulatory depression
- respiratory arrest
- shock and cardiac arrest
- central nervous system: insomnia, agitation, disorientation, Euphoria (state of excitement), Dysphoria (state of dissatisfaction), weakness
- cardiovascular: flushing of the face, bradycardia (slow heart rate), palpitation (feel your heart beat), faintness, and syncope, hypotension (low blood pressure)
- allergic: pruritus, urticaria (skin rashes)
- dizziness
- light-headedness
- nausea
- vomiting
- sweating
- dry mouth
- constipation
- headache
- visual disturbances
- low blood pressure
- problem with urine flow

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 Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of ASEPTONE SYRUP

- Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a place where the temperature stays below 25°C. Protect from light.

Do not store ASEPTONE SYRUP 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.

Product Description

- What it looks like

A red coloured syrup.

- Ingredients

Active ingredient

Each 1ml of syrup contains

5mg of methadone.

Inactive ingredients

- Methyl paraben
- Propyl paraben
- Rhodigel 23
- Sodium saccharin
- Propylene glycol
- Citric acid
- Ponceau 4R
- DI water
- Liquid glucose
- Coarse sugar

- MAL number

MAL05041880AZ

Manufacturer

DUOPHARMA (M) SDN.

BHD. (42491-M)

Lot. 2599, Jalan Seruling 59,

Kawasan 3, Taman Klang Jaya,

41200 Klang, Selangor Darul

Ehsan, Malaysia.

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