



METHADONE SYRUP

Methadone Hydrochloride (5mg/ml)

Consumer Medication Information Leaflet (RIMUP)

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What SW Methadone Syrup is used for

This medicine is used for the treatment of addiction in opioid drugs.

How SW Methadone Syrup Works

SW Methadone 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 SW Methadone Syrup

- When you must not use it

Do not take SW Methadone Syrup:

- If you have known hypersensitivity to methadone or any other opioid medication or any of the other ingredients listed at the end of this leaflet.
- If you suffer from a lung disorder such as asthma or any illness causing difficulty in breathing.
- If you have a recent head injury or increased pressure in the head
- If you are taking, or have taken in the last two weeks, medication for depression known as Monoamine Oxidase Inhibitors (MAOIs).
- If you take non-opioid drug dependence.
- If you have asthma attack.
- If you have hypersensitivity to the hydroxybenzoates.

Symptoms of an allergic reaction may include shortness of breath, wheezing, and difficulty in breathing, swelling of the face, lips, tongue or any other parts of the body, rash, itching or hives on the skin.

Uses during labor is not recommended, the prolonged duration of action increases the risk of neonatal depression. Methadone is not suitable for children.

- Before you start to use it

You should check with your doctor:-

- If you have liver or kidney problem.
- If you have underactive thyroid gland.
- If you have prostate problem.
- If you are elderly or ill patient.
- If you have constipation.
- If you have heart problem (cardiac conduction abnormalities, advanced heart disease or ischaemic heart disease).
- If you have electrolyte abnormalities.

Please consult your doctor before start to use SW Methadone 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 Methadone syrup against the benefits they expect it will have for you.

- Taking other medicines

There are a few medicines which may not mix with Methadone. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. You should talk to your doctor or pharmacist if you are on the following;

- Alcohol
- Rifampicin and Ciprofloxacin, medicine used to treat infection
- Anticonvulsants, medicines for seizure such as Phenytoin, Carbamazepine, Primidone
- Monoamine Oxidase (MAO) Inhibitors, medicines for depression
- Urinary Acidifiers
- Central Nervous System Depressants and Opioid Agonist Analgesics
- Naloxone, medicine for narcotic overdose
- Naltrexone, medicine for opioid addiction
- Antiviral, medicines used for HIV
- Buprenorphine/Pentazocine,
- Cimetidine, Medicine for gastric
- Azole antifungal agents, medicines for fungal infection

Taking SW Methadone Syrup with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medication.

How to use SW Methadone Syrup

- How much to use

You should take SW Methadone Syrup exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

Oral administration.

Adults: Initially 10 – 20 mg per day, increasing by 10 - 20 mg per day until there is no signs of withdrawal or intoxication. The usual dose is 40 - 60mg per day. The dose is adjusted according to the degree of dependence with the aim of gradual reduction.

- When to use it

Refer to your doctor or pharmacist.

- 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

Do not take extra dose to make up for a missed dose. Just take your next dose at usual the time.

- If you use too much (overdose)

If you take too many syrups by mistake, contact your doctor immediately or seek medical attention. Some of symptoms of overdose are :

- 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 (SW Methadone Syrup)**- Things you must do**

Take SW Methadone Syrup exactly the way as prescribed.

- Things you must not do

Do not share your medicine with others even if they have the same condition as you.

- Things to be careful of

- **Serotonin syndrome** : SW Methadone Syrup may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.
- **Adrenal insufficiency** : Long-term use of SW Methadone Syrup may cause adrenal insufficiency, a potentially life-threatening condition that may present with non-specific symptoms and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.
- **Infertility** : Long-term use of SW Methadone Syrup may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Be careful driving or operating machinery until you know how SW Methadone Syrup affects you.

Side Effects

Like all medicines, SW Methadone syrup can cause side effects, although not everybody gets them. Methadone has the potential to increase intracranial pressure, particularly in circumstances where it is already raised. Respiratory depression, exacerbation of existing asthma, low blood pressure, low blood sugar, nausea, vomiting, constipation, difficulty in urination, ureteric or biliary spasm, mouth dryness, drowsiness, feeling unhealthy and uncomfortable, hallucinations, mood change, slow heart action, irregular heart rate, rashes, itchiness on skin, dependence, decreased libido (low sexual desires) and contraction of pupil of eye have occasionally been reported. Tolerance to some of these side effects has been found to develop. Long-term administration may produce excessive sweating and raised prolactin levels.

Cases of QT prolongation and torsades de pointes (irregular heart rhythm) have been rarely reported.

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 visiting the website nptra.moh.gov.my [Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of SW Methadone Syrup**- Storage**

Store at below 30°C. Protect from light.

- Disposal

If you have any unwanted medicine, do not put them in waste water or household rubbish. Ask your pharmacist how to dispose syrup. These measures will help to protect the environment.

Product Description**- What it looks like**

Red colour syrup without flavor.

- Ingredients

- Active Ingredient

- Methadone Hydrochloride

- Inactive Ingredients

- Methyl Paraben
- Propyl Paraben
- Sodium Benzoate
- Ponceau C 4R
- Propylene Glycol
- Sugar

-MAL number

MAL08031395AZ

Manufacturer & Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd.
No. 9,11 & 17, Jalan Kempas 4,
Taman Perindustrian Tampoi Indah,
81200 Johor Bahru, Johor, Malaysia.

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