

Package Leaflet: Information for the user

Phymet DTF 1 mg/ml Syrup

methadone hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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1. What Phymet is and what it is used for

Phymet DTF 1 mg/ml Syrup contains the active substance methadone hydrochloride and belongs to a group of medicines called opioid analgesics. The opioid class of drugs includes the commonly known morphine and codeine which are obtained by a doctor's prescription. The opioid class of drugs also includes illegal drugs such as heroin. Phymet DTF 1 mg/ml Syrup works like other opioid drugs, but tends to have a longer life in the body, stopping the withdrawal symptoms that can occur during your treatment.

Phymet is used for:

- Relief of pain in adults with conditions where morphine may be a reasonable alternative, such as severe cancer pain.
- Treatment of adults with opioid drug dependency.

If you have any questions about why you are taking Phymet DTF 1mg/ml Syrup ask your doctor or pharmacist.

2. What you need to know before you use Phymet

Do not take Phymet if:

- you are allergic (hypersensitive) to methadone, methadone hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- you are suffering from breathing difficulties, in particular asthma.
- you are suffering from alcoholism.
- you have suffered a recent head injury or increased pressure in the head.
- you are taking monoamine oxidase inhibitors (MAOIs) or if you have taken them within the last 2 weeks.
- you are suffering from a bowel condition such as ulcerative colitis.
- you are suffering from an abnormal reduction in liver function.
- you are suffering from a kidney condition such as renal tract spasm.
- you are suffering from pain under the right rib cage, usually after a meal.
- during labour.

Warnings and precautions

- It is important to understand that Phymet DTF 1 mg/ml Syrup is addictive. Speak to your doctor about this.

Please tell your doctor or pharmacist immediately if you notice:

- Your breathing is slower or shallower than normal.
- Your heart beat is slower or is irregular.

If you suffer from any of the following medical conditions, tell your doctor before taking this medicine:

- Heart disease.
- Liver disease.
- Low level of potassium in your blood (hypokalaemia).
- Imbalances in your body salts (electrolytes)
- Family history of sudden death
- Hypothyroidism -a condition in which the body lacks sufficient thyroid hormone.
- Adrenocortical insufficiency -a condition in which the adrenal glands do not produce adequate amounts of steroid hormones.
- Hypopituitarism – a condition in which there is a decline in the level of hormones produced by the pituitary gland.
- An enlarged prostate gland.
- Shock – a condition in which there is a dramatic reduction in blood flow.
- Low blood pressure.
- Inflammatory or obstructive bowel disorders.
- Muscle weakness (myasthenia gravis)
- A tumour of the adrenal gland known as phaeochromocytoma.
- Renal dysfunction – also known as kidney disease.
- An intolerance to some sugars

Some patients may develop a condition called hypocortisolism as a result of taking Phymet. You should contact your doctor immediately if you experience symptoms such as fatigue, weakness, weight loss, nausea, vomiting, and/or diarrhoea (see section 4).

It is important that your doctor knows if you suffer from any other medical conditions

Other medicines and Phymet

Tell your doctor if you are taking:

- Strong painkillers commonly referred to as opioids
- Medication to reduce the acid in your stomach (Histamine H2 antagonists)
- Medicine to treat tuberculosis (rifampicin)
- Medication to treat HIV infection (particularly nevirapine, efavirenz and some protease inhibitors)
- Medication to control seizures (phenytoin, carbamazepine)
- Medication to treat depressive illness (tricyclic antidepressants) or obsessive compulsive disorder (fluvoxamine).
- Medications to treat heart arrhythmia such as amiodarone, diltiazem, disopyramide, procainamide, sotalol, verapamil.
- Medication known as monoamine oxidase inhibitors, such as linezolid, moclobemide, phenelzine, tranylcypromine (or have taken them in the last 14 days).
- Certain hormones (mineralocorticoid hormones)
- Certain antibiotics (macrolides antibiotics, ciprofloxacin)
- Certain antifungals (azole antifungals)
- Certain psychotropic drugs
- Neuromuscular blocking agents
- Any medicine that may be affected by reduced gastric mobility
- Any substance that may affect the acidity of your urine.

- St. John's Wort, tranquillisers (e.g. benzodiazepines), barbiturates, phenothiazines, diuretics, laxatives, cimetidine, nelfinavir, zidovudine, fluconazole and desipramine, abacavir or amprenavir, grapefruit juice.

Some patients may develop a condition called serotonin syndrome, particularly if they are also taking other antidepressant medicines such as SSRIs (citalopram, fluoxetine), SNRIs (duloxetine, venlafaxine, sibutramine) or tricyclic antidepressants (amitriptyline, clomipramine, imipramine, nortriptyline). The following are symptoms of this condition: Feeling very agitated or irritable, feeling confused, feeling restless, feeling hot, sweating, shaking, shivering, hallucinations (strange visions or sounds), muscle stiffness, sudden jerks of the muscles or a fast heartbeat. The severity can increase, leading to loss of consciousness. If you notice any of these symptoms, contact your doctor (see section 4).

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Check with your doctor or pharmacist before you start to take any other medicine, or other substance, by any route. Failure to do so can be dangerous.

Taking Phymet with food and drink

If you intend to drink alcohol while you are taking Phymet DTF 1 mg/ml Syrup, speak to your doctor.

Pregnancy, breast-feeding and fertility

Do not use Phymet during pregnancy.

Use during labour is not recommended.

Ask your doctor or pharmacist for advice before breast-feeding your baby.

Long-term use may decrease sex hormone levels, which could cause fertility problems.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

This product may cause drowsiness. It is recommended that you don't drive, use machinery or undertake any activities where alertness is required. The time after which it is safe to do so depends on each individual. Discuss your own situation with your doctor.

Phymet DTF 1 mg/ml Syrup contains:

This product contains sunset yellow (E110) and methyl para-hydroxybenzoate (E218) which may cause allergic reactions (sometimes delayed). If you have an intolerance to some sugars, you should contact your doctor before you take this medicine as it contains maltitol, and sorbitol. Maltitol may have a mild laxative effect and has a calorific value of 2.3 kcal/g. This product also contains glycerol which may cause headache, stomach upset and diarrhoea.

This medicinal product contains 0.3% ethanol (alcohol), i.e. up to 240 mg per dose, equivalent to approximately 7.2 ml beer or 3 ml wine per dose. This product may be harmful for those suffering from alcoholism, pregnant or breast-feeding women, children or high risk patients, such as those with liver disease or epilepsy.

3. How to use Phymet

Phymet DTF 1 mg/ml Syrup is designed specifically to be taken by mouth only. IT IS NOT SUITABLE FOR INJECTION. Injecting Phymet DTF 1 mg/ml Syrup can be extremely dangerous.

Instructions for use

Phymet DTF 1 mg/ml Syrup is usually taken in a single daily dose. The dose is specifically worked out for you by your doctor to stop you experiencing any withdrawal symptoms. Your

dose is usually taken at the clinic or pharmacy under the guidance of a pharmacist or dispenser. Take Phymet DTF 1 mg/ml Syrup as directed by your doctor or pharmacist. They will tell you how much syrup to take at each dose and when to take your dose each day. For take-home doses, the label on your bottle will give you the same information. If you have any questions about the dose that you have been prescribed, or if there is something that you do not understand, ask either your doctor or pharmacist. Phymet DTF 1 mg/ml Syrup is only effective if you take the treatment daily, since withdrawal symptoms can still occur.

Phymet DTF Syrup is not recommended for use in children and adolescents aged less than 18 years.

If you take more Phymet than you should

Your dose is usually taken at the clinic or pharmacy under the guidance of a pharmacist or dispenser. So it is unlikely that you will take too much. For take-home doses, the dosage is specifically worked out for you. If you think that you have taken too much, or if anyone else has taken your medicine by mistake, immediately contact your doctor or go to your nearest hospital casualty department. You are likely to need urgent medical attention even though you may feel well. Take this leaflet or your medicine with you so that the hospital will know what you have taken.

If you forget to take Phymet

If you have forgotten to take one or more doses of your take-home doses, contact your doctor or pharmacist for advice. Do not take a double dose to make up for a forgotten dose.

If you stop taking Phymet

Withdrawal symptoms, usually mild, may be observed after discontinuation and include: Body aches, diarrhoea, erection of the hair on the skin, eating disorders, nervousness or restlessness, sneezing, runny nose, tremors or shivering, abdominal cramps, nausea, sleep disturbance, increase in sweating and yawning, weakness and unexplained fever. Some people may notice that their heart is beating a little faster or more forcefully. With appropriate dose adjustments and gradual withdrawal these symptoms are usually mild. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Seek medical advice immediately if you notice breathing difficulty or any other signs of an overdose. Some people can be allergic to medicines. If you have any of the following symptoms soon after taking Phymet DTF 1 mg/ml Syrup, STOP taking this medicine and tell your doctor immediately.

- Sudden wheezing and chest pain or tightness.
- Swelling of eyelids, face or lips.
- Lumpy skin rash or 'hives' anywhere on the body.

Seek medical attention immediately if you develop any symptoms of serotonin syndrome such as: Agitation, hallucinations, rapid heart rate, fever, excessive sweating, shivering or shaking, muscle twitching or stiffness, trouble with coordinating, nausea, vomiting or diarrhoea.

Also seek medical attention if you experience symptoms of adrenal insufficiency such as: Nausea or vomiting, loss of appetite, fatigue, weakness, dizziness, low blood pressure.

Inform your health care professional if you experience signs or symptoms of decreased sex hormone levels such as low libido, impotence, erectile dysfunction, lack of menstruation or infertility.

Other side effects are listed below:

Very common (affects more than 1 person in 10)

Dizziness, drowsiness, light-headedness, nausea, vomiting, dry mouth, constipation, sweating.

Common (affects less than 1 person in 10)

Confusion, difficulty with or an inability to urinate. An exaggerated sense of well being has been reported at higher doses.

Rare (affects less than 1 person in 1000)

Low blood pressure and collapse. Heart beat is slower or is irregular.

Less common side effects include, spasms in the kidney and liver, breast enlargement in males, palpitations, irregular heart beat or affect of your breathing, fainting, contraction of pupils, sexual dysfunction.

Studies in men on methadone have shown that methadone reduces testosterone levels, ejaculate volume and sperm motility.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Phymet

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Phymet DTF 1 mg/ml Syrup contains

- The active substance is methadone hydrochloride.
- The other ingredients are glycerol, methyl para-hydroxybenzoate (E218), sodium benzoate (E211), maltitol solution, flavour spice IFF 17.40.1831, sunset yellow (E110), brilliant blue (E133), purified water, ethanol.

What Phymet DTF 1 mg/ml Syrup looks like and contents of the pack

Phymet DTF 1 mg/ml Syrup is a clear, green syrup. Each bottle contains 500 ml of syrup. Each ml of syrup contains 1 mg of methadone hydrochloride.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: GlaxoSmithKline (Ireland) Ltd., 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.
Manufacturer: Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany

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