

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:

- 1. What Phymet is and what it is used for**
- 2. What you need to know before you use Phymet**
- 3. How to use Phymet**
- 4. Possible side effects**
- 5. How to store Phymet**
- 6. Contents of the pack and other information**

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 or COPD.
- you are suffering from alcoholism.
- you are suffering from a tumour of adrenal gland tissue known as phaeochromocytoma.
- 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.
- you are dependent on any other drugs.
- you are at risk of having a bowel disorder known as paralytic ileus.

Warnings and precautions

Tolerance, dependence, and addiction

- This medicine contains methadone which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Phymet DTF 1 mg/ml Syrup can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.
- Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. When used for the treatment of pain, you might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain
- The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Phymet DTF 1 mg/ml Syrup if:
 - You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
 - You are a smoker.
 - You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.
- If you notice any of the following signs whilst taking Phymet DTF 1 mg/ml Syrup, it could be a sign that you have become dependent or addicted.
 - You need to take the medicine for longer than advised by your doctor
 - You need to take more than the recommended dose
 - You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
 - You have made repeated, unsuccessful attempts to quit or control the use of the medicine
 - When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')
- If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Phymet DTF 1 mg/ml Syrup).

Talk to your doctor, pharmacist or nurse if you experience any of the following symptoms while taking Phymet DTF 1 mg/ml Syrup:

- Your breathing is slower or shallower than normal.
- If you have asthma and it gets worse.
- Your heart beat is slower or is irregular.
- Pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.
- Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) or the biliary tract system.
- You have developed a more general pain throughout your body than the specific pain you are treating with Phymet DTF 1 mg/ml Syrup.

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)
- Renal dysfunction – also known as kidney disease.
- An intolerance to some sugars
- You are extremely ill or an older person. You may be more sensitive to the medicine.

Sleep-related breathing disorders

- Phymet DTF 1 mg/ml Syrup can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Phymet:

Weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenals producing too little of the hormone cortisol, and you may need to take hormone supplement (see section 4).

Long-term use may cause decreased sex hormone levels and increased levels of the hormone prolactin. Contact your doctor if you experience symptoms such as decreased libido, impotence, erectile dysfunction, absence of menstruation (amenorrhea) or infertility.

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 any of the following medicines:

- Strong painkillers commonly referred to as opioids (pentazocine)
- Medication used to reduce opioid withdrawal symptoms (lofexidine, clonidine)
- Medication used to reverse the effect of opioid drugs (naloxone)
- Medication used to stop opioid drugs working (naltrexone, buprenorphine)
- 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 treat seizures (cannabidiol)
- Medication to control seizures (phenytoin, phenobarbital, carbamazepine, primidone)
- Medicines used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin can increase the risk of opioid overdose, respiratory depression (breathing difficulties) and may be life-threatening).
- Medication to treat depressive illness (fluoxetine, tricyclic antidepressants e.g. desimipramine), obsessive compulsive disorder (fluvoxamine) or anxiety.
- Medications to treat heart arrhythmia such as amiodarone, diltiazem, disopyramide, procainamide, sotalol, verapamil, mexiletine.

- Medication known as monoamine oxidase inhibitors, such as linezolid, moclobemide, phenelzine, tranylcypromine (or have taken them in the last 14 days).
- Antihistamines with sedative effect (e.g. cyclizine)
- Certain hormones (mineralocorticoid hormones)
- Certain antibiotics (macrolides antibiotics e.g. erythromycin, ciprofloxacin)
- Certain antifungals (azole antifungals e.g. ketoconazole)
- Certain psychotropic drugs
- Certain pain, spasm and fever-treatment drug (metamizole)
- 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), sedatives, barbiturates, phenothiazines, diuretics, laxatives, cimetidine, nelfinavir, zidovudine, fluconazole and desipramine, abacavir or amprenavir, grapefruit juice.
- Sleep medication (benzodiazepines, chloral hydrate and chlormethiazole).
- Medications used to treat nausea and vomiting (domperidone, metoclopramide).

The risk of side effects increases, if you use methadone concomitantly with antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine, amitriptyline, clomipramine, imipramine, nortriptyline). Contact your doctor if you experience symptoms such as:

- mental-status changes (e.g. agitation, hallucinations, coma)
- fast heartbeat, unstable blood pressure, fever
- exaggeration of reflexes, impaired coordination, muscle stiffness
- gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea)

Concomitant use of Phymet and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Phymet together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

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.

Grapefruit juice may affect how Phymet DTF 1 mg/ml Syrup works.

Pregnancy, breast-feeding and fertility

Do not use Phymet during pregnancy. Newborn babies to mothers taking Phymet DTF 1 mg/ml Syrup are at risk of developing withdrawal symptoms, eye disorders and respiratory depression.

Some studies have reported birth defects or neurodevelopmental problems (problems with

early childhood development) in children born to mothers who used methadone during pregnancy to treat opioid addiction. However, it is not possible to determine if this is caused by methadone use or other factors such as the health of the mother and social and environmental conditions associated with opioid addiction.

Use during labour is not recommended.

Take care if you are taking a pregnancy test as the methadone may interfere with the results. Talk to your doctor if you are breast-feeding or thinking of breast-feeding while you are taking methadone as it may affect your baby. Monitor your baby for abnormal signs and symptoms such as increased drowsiness (more than usual), breathing difficulties or limpness. Consult your doctor immediately if you notice any of these symptoms.

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:

- **Sunset yellow (E110)** which may cause allergic reactions.
- **Brilliant blue (E133)** which may cause allergic reactions.
- **Methyl para-hydroxybenzoate (E218)** which may cause allergic reactions (possibly delayed).
- **Maltitol** which may have a mild laxative effect and has a calorific value of 2.3 kcal/g. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- **Sorbitol:** this medicine contains 52 mg sorbitol in each ml. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.
- **Glycerol** which may cause headache, stomach upset and diarrhoea.
- **Sodium benzoate:** this medicine contains 1 mg sodium benzoate in each ml.
- **Ethanol:** this medicine contains 2 mg of alcohol (ethanol) in each ml. The amount in a maximum daily dose of 120 ml of this medicine is equivalent to less than 6 ml beer or 2.4 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- **Sodium:** this medicine contains less than 1 mmol sodium (23 mg) per a maximum daily dose of 120 ml, that is to say essentially 'sodium-free'.

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.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Phymet DTF 1 mg/ml Syrup, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also if you stop taking Phymet DTF 1 mg/ml Syrup).

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.

If you take too much Phymet you can experience brain disorder (known as toxic leukoencephalopathy).

If you take more Phymet than you should, it can result in low blood sugar.

The signs of serious overdose are difficulty in breathing; feeling very drowsy which may lead to stupor or coma; very small pupils; cold and clammy skin; a very slow pulse rate; low blood pressure and muscle weakness. In extreme cases, you may stop breathing, your blood flow may stop, you may have a heart attack which could lead to death.

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

Do not stop taking Phymet until your doctor tells you to.

When stopping Phymet, your doctor will help you to reduce your dose slowly over an appropriate period of time.

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 healthcare 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 (may affect more than 1 in 10 people)

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

Common (may affect up to 1 in 10 people)

Confusion, exaggerated sense of well-being, hallucinations, difficulty with or an inability to urinate. Rash that may appear and disappear, sweating, water retention, blurred vision, dry eyes, contraction of pupils, spinning and loss of balance sensation (Vertigo), weight gain.

Uncommon (may affect up to 1 in 100 people)

Worsening of asthma symptoms, inflammation of the tongue, state of unease and dissatisfaction (dysphoria), dependence, agitation, disorientation, difficulty sleeping, headache, fainting, facial flushing, low blood pressure, excess fluid in the lungs, dry nose, slow or shallow breathing, itchy skin, rash. Swollen arms and legs, which may be sign of your body holding more water than usual. Feeling weak, tired, low body heat (hypothermia), low libido, drug withdrawal symptoms.

Rare (may affect up to 1 in 1,000 people)

Collapse, heart beat is slower or is irregular, feeling an unusual heartbeat (palpitations).

Frequency not known: frequency cannot be estimated from the available data

You can become dependent on Phymet (for more information see section 2 Warnings and Precautions). Low blood sugar, reduction in blood platelets, which increase the risk of bleeding or bruising. Loss of appetite, low potassium and magnesium levels found in blood tests, production of breast milk, low blood sugar. Rapid, uncontrollable movements of the eyes, crossed eyes, visual disturbances. Sleep apnoea (breathing pauses during sleep). Spasms in the kidney and liver, breast enlargement in males or sexual dysfunction. Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

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, Website: www.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.
- Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.
- 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 (contains sorbitol), flavour spice IFF 17.40.1831 (contains ethanol), sunset yellow (E110), brilliant blue (E133), purified water.

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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