Package leaflet: Information for the patient

Molterfin 2 mg sublingual tablets
Molterfin 8 mg sublingual tablets

buprenorphine

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 Molterfin is and what it is used for

Molterfin contains the active substance buprenorphine.

Molterfin is used:

- if you are addicted to opioids, e. g. heroin or morphine, within a framework of medical, social and psychological treatment.

The treatment is prescribed and monitored by doctors specialized in treating drug addiction.

2. What you need to know before you take Molterfin

Do not take Molterfin if you:
- are allergic to buprenorphine or any of the other ingredients of this medicine (listed in section 6).
- suffer from serious breathing difficulties
- suffer from a seriously reduced liver function
- suffer from alcoholism or delirium tremens.

Warnings and precautions
Talk to your doctor or pharmacist before taking Molterfin if you:
- have taken morphine or heroin (opioids) less than 6 hours ago, as withdrawal symptoms can occur
- have taken methadone less than 24 hours ago, as withdrawal symptoms can occur (if you use methadone your dose may have to be adjusted before you take buprenorphine, see section 3)
- suffer from asthma or breathing difficulties

- suffer from reduced function of the kidneys or the liver. If you suffer from serious liver insufficiency you must not take buprenorphine
- suffer from low bloodpressure
- have difficulty passing urine (because of an enlarged prostate gland or urethral stricture)
- suffer from a head injury and have an increased intracranial pressure

Misuse, abuse and diversion
Serious cases of infections with potential fatal outcome may occur in context of misuse of Molterfin, when taken by intravenous route.

Observe that Molterfin may:
- cause dependence
- cause your blood pressure to drop suddenly, causing you to feel dizzy and unwell if you get up too quickly from sitting or lying down
- mask other diseases where pain is a symptom since buprenorphine has a pain relieving effect.

Children and adolescents
Children and adolescents below 18 years of age must not take this medicine.

Other medicines and Molterfin
Buprenorphine may influence the effect of other medicines and other medicines may influence the effect of buprenorphine.
It is therefore important you tell your doctor if you use any of the following medicines:
- medicine used in the treatment of anxiety and disquiet and sleeping difficulties (benzodiazepines and anxiolytics other than benzodiazepines)
- medicine used in the treatment of skin infection in the scalp (ketoconazole, itraconazole)
- medicine used in the treatment of certain infections (rifampicin)
- medicine used in the treatment of HIV (ritonavir, indinavir, nelfinavir)
- some types of medicine used in the treatment of allergy
- some types of medicine used in the treatment of depression
- medicine used in the treatment of migraine, hot flushes and abstinences as a result of medicine abuse (clonidine)
- cough medicine (dextromethorphan, noscapine)
- painkillers (morphine and morphine-like substances)
- medicine containing alcohol
- medicine used in the treatment of epilepsy (phenobarbital, phenytoin, carbamazepine)
- medicine used in the treatment of psychosis (neuroleptics)
- medicine used as sedatives and to relieve convulsions (barbiturates).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking Molterfin with food, drink and alcohol
You can take Molterfin independently of a meal (see Section 3).
Do not drink alcohol when you are treated with Molterfin since alcohol will increase the sedative effect of buprenorphine.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You should not use buprenorphine during your pregnancy. But if your doctor finds it appropriate an exception can be made for the first 3 months of your prenancy.

Breast-feeding
Do not take buprenorphine if you are breast-feeding.

Driving and using machines
Molterfin can be sedating, cause fainting and dizziness, and therefore it can reduce the ability to drive and use machines.
Do not drive or use machines if you feel dizzy or drowsy. This usually occurs at the beginning of treatment and when the dose is increased.

Molterfin contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Molterfin

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

This is the way you take Molterfin
A sublingual tablet is a tablet that is taken under your tongue. Keep the tablet dose under your tungue until it dissolves – normally it takes 5-10 minutes. Do not swallow, crush or chew the tablet.
You can take Molterfin independently of a meal.

Usual dose if you are/have:
- *Adults or elderly:*
  Your doctor **will decide your initial dose** and increase your dose according to your response to the treatment until you have a stabil dose, 16 mg daily is often sufficient. The maximum daily dose is 24 mg. Your doctor will then individually determine the length of your treatment and gradually reduce your dose. Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you.

- *Children and adolescents (younger than 18 years):*
  Children and adolescents under the age of 18 must not use Molterfin.

- *Recuced kidney or liver function:*
  If you have problems with your kidneys or liver your dose may have to be reduced. Talk to your doctor. If you suffer from serious liver insufficiency you must not take buprenorphine.

- *Concomitant methadone treatment*
  Your dose of methadone has to be reduced to a maximum of 30 mg daily before starting treatment with Molterfin. Contact your doctor if you experience withdrawal symptoms (sweating, disquiet or restlessness).

If you take more Molterfin than you should
In case of overdose of buprenorphine, you must go or be taken immediately to an emergency centre or hospital for treatment.
Symptoms of an overdose is breathing difficulties, slowly breathing or heart symptoms.

Toxic poisoning has been observed after misuse (overdose or wrong administration) and in worst case it can result in stop of breathing/heart failure and/or liver damage.

If you forget to take Molterfin
Do not take a double dose to make up for a forgotten dose.

If you stop taking Molterfin
Do not stop the treatment yourself, but ask your doctor how to end the treatment.
A sudden interruption can cause withdrawal symptoms (sweating, disquiet and restlessness).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should stop taking Molterfin and see your doctor immediately if you experience symptoms of angioneurotic oedema (rare side effect), such as:
- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulties to breath

Addiction to Molterfin
Please observe that Molterfin may cause dependence.

Common side effects (occuring in more than 1 but less than 10 in 100 patients):
- Headache, fainting, dizziness
- Obstipation, nausea, vomiting
- Insomnia, drowsiness, feeling of weakness
- Drop in blood pressure on changing position from sitting or lying down to standing
- Sweating.

In long term use of buprenorphine, the common undesirable effects diminish successively. However constipation and sweating often remain.

Rare side effects (occurring in more than 1 but less than 10 in 10,000 patients):
- Hallucinations
- Respiratory depression, bronchial spasm
- Damage of the liver, hepatitis
- Anafylatic shock, angioneurotic oedema
- Urine retention

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Molterfin

Keep this medicine out of the sight and reach of children.

Do not use Molterfin after the expiry date which is stated on the carton and on the blister after EXP.The expiry date refers to the last day of that month.

Does not require any special storage conditions.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Molterfin contains
- The active substance is buprenorphine as buprenorphine hydrochloride.
- Each 2 mg sublingual tablet contains 2 mg buprenorphine.
- Each 8 mg sublingual tablet contains 8 mg buprenorphine.
- The other ingredients are lactose monohydrate, mannitol (E421), maize starch, citric acid (E330), sodium citrate (E331), povidone (E1201), magnesium stearate (E470b).

What Molterfin looks like and contents of the pack
Molterfin 2 mg is an oval, biconvex and white sublingual tablet with “2” embossed on one side.
Molterfin 8 mg is an oval, biconvex and white sublingual tablet with “8” embossed on one side.

Molterfin is packed in strips of 7, 14 and 28 sublingual tablets and in a bundle pack for hospital use with 140 (5 x 28) sublingual tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
[To be completed nationally]

Manufacturer
Fine Foods & Pharmaceuticals N.T.M. S.p.A.
Via Grignano 43
24041 Brembate (Bergamo)
Italy

L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A.
Strada Statale 67
Fraz. Granatieri
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Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Italy:	Buprenorfina Molteni
Poland:	Bunorfin
Sweden:	Molterfin

This leaflet was last revised in 23 August 2019.