Package leaflet: Information for the user

Enolwen 5 mg/2.5 mg prolonged-release tablets
Enolwen 10 mg/5 mg prolonged-release tablets
Enolwen 20 mg/10 mg prolonged-release tablets
Enolwen 40 mg/20 mg prolonged-release tablets

oxycodone hydrochloride / naloxone 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 Enolwen is and what it is used for

Enolwen is a prolonged-release tablet, which means that its active substances are released over an extended period. Their action lasts for 12 hours.

Pain relief
You have been prescribed Enolwen for the treatment of severe pain, which can be adequately managed only with opioid analgesics. Naloxone is added to counteract constipation.

How Enolwen works in pain relief

Enolwen tablets contain oxycodone and naloxone as active substances. Oxycodone is responsible for the painrelieving effect of Enolwen. It is a strong analgesic (“painkiller”) that belongs to a group of medicines called opioids. Naloxone is intended to counteract constipation. Constipation is a typical side effect of treatment with opioid painkillers.

Restless legs syndrome
You have been prescribed Enolwen for the second line symptomatic treatment of severe to very severe restless legs syndrome in people who can’t be treated with dopamine medicines. People with restless legs syndrome have unpleasant sensations in their limbs. This can start as soon as they sit or lie down and is only relieved by an irresistible urge to move the legs, sometimes the arms and other parts of the body. It makes sitting still and sleeping very difficult. Naloxone hydrochloride is added to counteract constipation.

How Enolwen works in restless legs syndrome

These tablets help to relieve the unpleasant sensations and so reduces the urge to move the limbs.
Naloxone is intended to counteract from constipation. Constipation is a typical side effect of treatment with opioid painkillers.

2. What you need to know before you take Enolwen

Do NOT take Enolwen tablets

- if you are allergic to oxycodone or naloxone or any of the other ingredients of this medicine (listed in section 6),
- if you have breathing problems, such as breathing more slowly or weakly than expected (respiratory depression),
- if you suffer from a severe lung disease associated with narrowing of the airways (chronic obstructive pulmonary disease or COPD),
- if you suffer from a condition known as cor pulmonale. In this condition the right side of the heart becomes enlarged, due to increased pressure inside blood vessels in the lung etc. (e.g. as a result of COPD – see above),
- if you suffer from severe bronchial asthma,
- if you have a type of bowel obstruction (paralytic ileus) not caused by opioids,
- if you have moderate to severe liver problems.

Additionally for restless legs syndrome

- if you have a history of opioid abuse.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Enolwen:

- in the case of elderly or debilitated (weak) patients,
- if you have a type of bowel obstruction (paralytic ileus) caused by opioids,
- if you have kidney problems,
- if you have mild liver problems,
- if you have severe lung problems (i.e. reduced breathing capacity),
- if you suffer with a condition characterised by frequent breathing stops during the night, which may make you feel very sleepy during the daytime (sleep apnoea),
- if you have myxoedema (a thyroid disorder, with dryness, coldness and swelling [‘puffiness’] of the skin, affecting the face and limbs),
- if your thyroid gland is not producing enough hormones (underactive thyroid, or hypothyroidism),
- if your adrenal glands are not producing enough hormones (adrenal insufficiency, or Addison’s disease),
- if you have a mental illness accompanied by a (partial) loss of reality (psychosis), due to alcohol or intoxication with other substances (substance-induced psychosis),
- if you suffer from gallstone problems,
- if your prostate gland is abnormally enlarged (prostate hypertrophy),
- if you are or ever have been addicted to alcohol or drugs, or have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping alcohol or drugs (delirium tremens),
- if your pancreas is inflamed (pancreatitis),
- if you have low blood pressure (hypotension),
- if you have high blood pressure (hypertension),
- if you have pre-existing heart disease,
- if you have a head injury (due to the risk of increased brain pressure),
- if you suffer from epilepsy or are prone to fits,
- if you are also taking a type of medicine known as a MAO inhibitor (used to treat depression or Parkinson’s disease), e.g. medicines containing tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid.
- if sleepiness or episodes of suddenly falling asleep occur.

Tell your doctor if any of the above has ever applied to you in the past. Also, please tell your doctor if you develop any of the above disorders while you are taking Enolwen.

These tablets are not recommended for use in patients with advanced digestive or pelvic cancers where bowel obstruction may be a problem.

Children and adolescents

This medicine must not be given to children or adolescents under 18 years of age as the safety and benefits have not been shown yet.

How to use Enolwen correctly

If you experience severe diarrhoea at the start of treatment (within the first 3-5 days) this may be due to the effect of naloxone. It may be a sign that your bowel movements are returning to normal. If diarrhoea persists after 3-5 days, or it gives you cause for concern, please contact your doctor.

If you have been using high doses of another opioid, withdrawal symptoms (such as restlessness, bouts of sweating or muscle pain) may occur when you initially switch to taking these tablets. If you experience withdrawal symptoms, you may need to be specially monitored by your doctor.

If you need to undergo surgery, please tell your doctor that you are taking this medicine.

If you have been taking this medicine for a long time, you may become tolerant. This means you may need a higher dose to achieve the desired effect. Long-term use of these tablets may also lead to physical dependence. Medicines containing oxycodone should be avoided in patients with a present or past abuse of alcohol, drugs or medicines. Withdrawal symptoms may occur if treatment is stopped too suddenly. If you no longer need treatment, you should reduce your daily dose gradually, in consultation with your doctor.

As with other strong opioid painkillers, there is a risk that you may develop a psychological dependence to oxycodone.

You may notice remains of the tablet in your stools. Do not be alarmed, as the active substances will have already been released in the stomach and gut, and absorbed into your body.

Incorrect use of Enolwen

Enolwen is not suitable for withdrawal treatment.

This medicine should never be abused, particularly if you have a drug addiction. If you are addicted to drugs such as heroin, morphine or methadone, severe withdrawal symptoms are likely if you abuse this medicine because it contains the ingredient naloxone. Pre-existing withdrawal symptoms may be made worse.

You should never misuse the tablets by dissolving and injecting them (e.g. into a blood vessel). They contain talc, which can cause destruction of local tissue (necrosis) and changes in lung tissue (lung granuloma). Misuse can also have other serious consequences which may be fatal.

Other medicines and Enolwen

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

The risk of side effects is increased if you take these tablets at the same time as medicines which affect the way the brain works. For example, you may feel very sleepy, or breathing problems (slow and shallow breathing) may get worse.

Examples of medicines that affect the way the brain works include:

- other strong painkillers (opioids),
- sleep medication and tranquilisers (sedatives, hypnotics),

- antidepressants,
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics),
- other medicines which act on the nervous system (phenothiazines, neuroleptics).

Tell your doctor if you are taking:
- medicines that decrease the blood's clotting ability (coumarin derivatives), this clotting time may be speeded up or slowed down
- antibiotics of the macrolide type (such as clarithromycin)
- antifungal medicines of the –azole type (e.g. ketoconazole)
- ritonavir or other protease inhibitors (used to treat HIV)
- rifampicin (used to treat tuberculosis)
- carbamazepine (used to treat seizures, fits or convulsions and certain pain conditions)
- phenytoin (used to treat seizures, fits or convulsions).

Enolwen with food, drink and alcohol

Drinking alcohol whilst taking Enolwen may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you are taking Enolwen.

You should avoid drinking grapefruit juice while you are taking this medicine.

Pregnancy and breastfeeding

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

Pregnancy

Use of Enolwen during pregnancy should be avoided unless your doctor finds treatment with this medicine is essential. If used over prolonged periods during pregnancy, oxycodone may lead to withdrawal symptoms in the newborn baby. If oxycodone is given during childbirth, the baby may have breathing problems such as slow and shallow breathing (respiratory depression).

Breastfeeding

Breastfeeding should be stopped during treatment with this medicine as oxycodone (one of the active substances of this medicine) passes into breast milk and it is not known whether naloxone also passes into breast milk. Therefore, a risk for the breastfed infant cannot be excluded in particular following intake of multiple doses of this medicine.

Driving and using machines

This medicine can affect your ability to drive or operate machines as it may make you sleepy or dizzy. This is most likely at the start of your treatment, after a dose increase or after switching from a different medication. These side effects should disappear once you are on a stable dose.

This medicine has been associated with sleepiness and episodes of suddenly falling asleep. If you experience these side effects, you must not drive or operate machinery. You should tell your doctor if this occurs.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Enolwen contains lactose

Enolwen 5 mg/2.5 mg and 10 mg/5 mg contain lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Enolwen 5 mg/2.5 mg and 10 mg/5 mg.

3. How to take Enolwen

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

You must swallow the prolonged-release tablet whole, so as not to affect the slow release of oxycodone from the tablet. Do not break, chew or crush the prolonged-release tablets. Taking broken, chewed or crushed tablets may result in your body absorbing a potentially fatal dose of oxycodone (see under "If you take more Enolwen than you should").

Unless otherwise prescribed by your doctor, the usual dose is:

To treat pain

Adults

The usual starting dose is one Enolwen 10 mg/5 mg Depottablett every 12 hours.

Your doctor will decide how much you should to take every day and how to divide the total daily dose into morning and evening doses. The doctor will also decide on any necessary dose adjustment during treatment depending on your level of pain and individual sensitivity. You should be given the lowest dose needed for pain relief. If you have already been treated with opioids, your treatment with this medicine may be started at a higher dose.

The maximum daily dose is 160 mg oxycodone hydrochloride and 80 mg naloxone hydrochloride. If you need a higher dose, your doctor may give you additional oxycodone without naloxone. However, the maximum daily dose of oxycodone should not exceed 400 mg. The beneficial effect of naloxone on bowel movements may be affected if additional oxycodone is given without additional naloxone.

If you experience pain between doses of Enolwen, you may need to take an additional fast-acting painkiller. Enolwen is not suitable for this. Please talk to your doctor.

If you feel that these tablets are too strong or too weak, please talk to your doctor or pharmacist.

To treat restless legs syndrome

Adults

The usual starting dose is one Enolwen 5 mg/2.5 mg Depottablett every 12 hours.

Your doctor will decide how much you should take every day and how to divide your total daily dosage into morning and evening doses. The doctor will also decide on any necessary dose adjustments during treatment. Your dose will be adjusted according to your individual sensitivity. You should be given the lowest dose needed to relieve your restless legs symptoms.
If you feel that these tablets are too strong or too weak, please talk to your doctor or pharmacist.
The maximum daily dose is 60 mg oxycodone hydrochloride and 30 mg naloxone hydrochloride.

To treat pain or restless legs syndrome

Elderly patients

In general, no dose adjustment is necessary for elderly patients with normal kidney and/or liver function.

Liver or kidney problems

If you have kidney or mild liver problems your doctor will prescribe Enolwen with special caution. You must not take these tablets if you have moderate or severe liver problems (see also Section 2 “Do not take Enolwentablets” and “Warnings and Precautions”).

Children and adolescents below 18 years of age

No studies have been carried out to show that this medicinework properly in children and adolescents, or are safe for them to take. It is therefore not recommended for use in patients under 18 years of age.

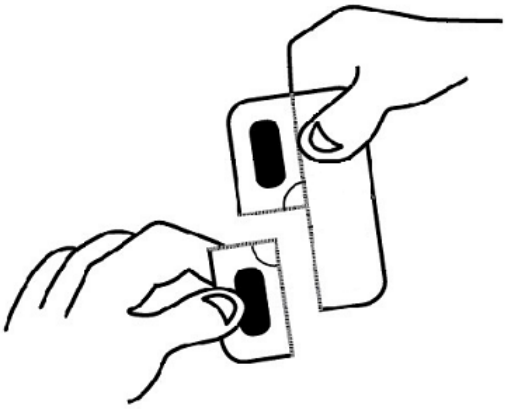
Method of administration

Swallow your tablets whole with a glass of water. You can take these tablets with or without food. Take them every 12 hours, according to a fixed time schedule. For instance, if you take a tablet at 8 o’clock in the morning, you should take your next tablet at 8 o’clock in the evening. Do not break, chew or crush the tablets.

Opening instructions

This medicinal product is in child-resistant packaging. The tablets cannot be pressed out of the blister. Please observe the following instructions when opening the blister.

1. Separate a single dose by carefully tearing along the perforated lines.



2. An unsealed corner is revealed at the intersection point of the perforated lines.

3. Slowly peel off the foil at the marked corner to unveil the pocket.

Duration of use

You should not take Enolwenfor any longer than you need to. If you have been taking the medicine for a long time your doctor should regularly check that you still need it.

If you take more Enolwen than you should

If you have taken more than the prescribed dose, you must inform your doctor immediately.

An overdose may result in:
- small (constricted) pupils,
- breathing more slowly or weakly than expected (respiratory depression),
- drowsiness or loss of consciousness,
- low muscle tone (hypotonia),
- reduced pulse rate and
- a fall in blood pressure.

In severe cases, loss of consciousness (coma), fluid on the lungs and circulatory collapse may occur, which may be fatal.

You should avoid situations which require you to be alert, e.g. driving.

If you forget to take Enolwen,

If you forget to take Enolwen or if you take a lower dose than the one prescribed, you may not feel any effect.

If you should forget to take your dose, please follow the instructions below:

- If your next usual dose is due in 8 hours or more: Take the forgotten dose immediately and continue with your normal dosing schedule.
- If your next usual dose is due in less than 8 hours: Take the forgotten dose, then, wait another 8 hours before taking your next dose. Try to get back in your normal dosing schedule (e.g. 8 o'clock in the morning and 8 o'clock in the evening).

Do not take more than one dose within any 8-hour period.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Enolwen

Do not stop taking your treatment without first consulting your doctor.

If you do not require any further treatment, your doctor will advise you how to reduce the daily dose gradually. In this way, you will avoid withdrawal symptoms, such as restlessness, bouts of sweating and muscle pain.

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.

Important side effects or signs to look out for, and what to do if you are affected:

Stop taking Enolwen and contact a doctor or go to your nearest emergency department immediately if you experience any of the following symptoms:

- A more slow or shallow breathing (respiratory depression). This is the most serious side effect with Enolwen and it mostly occurs in elderly and weak patients.
- Opioids can also cause a severe drop in blood pressure in susceptible patients.
- Swelling of the face, tongue or throat; difficulty swallowing; hives; breathing difficulties and drop in blood pressure (anaphylactic reaction)

Other side effects that may occur are:

The following side effects have been seen in patients being treated for pain

Common (may affect up to 1 in 10 people)

- Abdominal pain, indigestion, constipation, diarrhoea, wind
- Dry mouth
- Vomit (be sick), feel sick
- Decreased appetite up to loss of appetite
- A feeling of dizziness or ‘spinning’, vertigo
- Headache
- Hot flushes, sweating
- General weakness, tiredness or exhaustion
- Itchy skin, skin reactions/rash
- Difficulty in sleeping, drowsiness

Uncommon (may affect up to 1 in 100 people)

- Abdominal bloating
- Abnormal thoughts
- Anxiety, confusion, depression, nervousness, difficulties to concentrate
- Chest tightness especially if you already have coronary heart disease, chest pain
- Drop in blood pressure, rise in blood pressure
- Withdrawal symptoms such as agitation
- Fainting
- Palpitations
- Biliary colic
- Generally feeling unwell
- Pain
- Swelling of the hands, ankles or feet
- Impaired speaking
- Shaking
- Restlessness
- Difficulties breathing
- Chills
- Hepatic enzymes increased
- Runny nose

- Cough
- Hypersensitivity/allergic reactions
- Weight loss
- Injuries from accidents
- Increased urge to urinate
- Muscle cramps, muscle twitches, muscle pain
- Vision impairment
- Epileptic seizures (especially in persons with epileptic disorder or predisposition to seizures)

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

- Increase in pulse rate
- Dental changes
- Yawning
- Weight gain

Not known (cannot be estimated from the available data)

- Euphoric mood
- Severe drowsiness
- Erectile dysfunction
- Nightmares
- Hallucinations
- Shallow breathing
- Difficulties in passing urine
- Tingling in hands or feet
- Belching

The active substance oxycodone hydrochloride, if not combined with naloxone hydrochloride, is known to have the following differing sideeffects:

Breathing problems, such as breathing more slowly or weakly than expected (respiratory depression), reduction in size of the pupils in the eye, muscle cramps and decreased cough reflex.

Common (may affect up to 1 in 10 people)

- Altered mood and personality changes (e.g. depression, feeling of extreme happiness)
- Decreased activity, increased activity
- Difficulties in passing urine
- Hiccups

Uncommon (may affect up to 1 in 100 people)

- Impaired concentration, agitation
- Migraines
- Taste anomalies
- Increased muscle tension, involuntary muscle contractions
- Drug dependence, drug tolerance
- Ileus
- Dry skin, flushing of skin
-
- Reduced sensitivity to pain or touch
- Abnormal coordination
- Perception disturbances (e.g. hallucination, derealisation)
- Vocal changes (dysphonia)
- Water retention

- Difficulties in hearing
- Difficulties in swallowing
- Mouth ulcers, sore gums
- Reduced sex drive
- Dehydration, thirst

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

- Itching rash (urticaria)
- Herpes simplex
- Increased appetite
- Black (tarry) stools
- Gingival bleeding

Not known (frequency cannot be estimated from the available data)

- Acute generalised allergic (anaphylactic reactions)
- Absence of menstrual periods
- Problems with bile flow

The following side effects have been observed in patients treated for restless legs syndrome

Very common (may affect more than 1 in 10 people)

- Headache
- Drowsiness
- Constipation
- Feel sick
- Sweating
- Tiredness or exhaustion

Common (may affect up to 1 in 10 people)

- Decreased appetite up to loss of appetite
- Difficulty sleeping
- Difficulty in concentration
- Depression
- A feeling of dizziness or ‘spinning, vertigo
- Shaking
- Tingling in hands or feet
- Vision impairment
- Hot flushes
- Drop in blood pressure, rise in blood pressure
- Pain, abdominal pain, chest pain
- Dry mouth, thirst
- Vomit (be sick)
- hepatic enzymes increased (alanine aminotransferase increased, gamma-glutamyltransferase increased)
- Itchy skin, skin reactions/rash
- Chills

Uncommon (may affect up to 1 in 100 people)

- Reduced sexual drive
- Episodes of suddenly falling asleep
- Altered taste
- Difficulties breathing

- Wind
- Erectile dysfunction
- Withdrawal symptoms such as agitation
- Swelling of hands, ankles or feet
- Injuries from accidents

Not known (cannot be estimated from the available data)

- Hypersensitivity/allergic reactions
- Abnormal thoughts, hallucinations, nightmares
- Anxiety, confusion, nervousness, euphoric mood
- Restlessness
- Epileptic seizures (especially in persons with epileptic disorder or predisposition to seizures)
- Severe drowsiness, fainting
- Impaired speaking
- Chest tightness especially if you already have coronary heart disease
- Palpitations, increase in pulse rate
- Shallow breathing, yawning
- Cough
- Runny nose
- Abdominal bloating, diarrhoea, indigestion, belching
- Dental changes
- Biliary colic
- Muscle cramps, muscle twitching, muscle pain
- Difficulties in passing urine, increased urge to urinate
- Generally feeling unwell
- Weight loss, weight increase

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. 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 Enolwen

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 carton and blister after “EXP”. 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 throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Enolwen contains

The active substances are oxycodone hydrochloride and naloxone hydrochloride

5 mg/2.5 mg prolonged-release tablets

Each prolonged-release tablet contains 5 mg oxycodone hydrochloride, equivalent to 4.5 mg oxycodone and naloxone hydrochloride dihydrate, equivalent to 2.5 mg naloxone hydrochloride or 2.25 mg naloxone.

10 mg/5 mg prolonged-release tablets
Each prolonged-release tablet contains 10 mg oxycodone hydrochloride, equivalent to 9.0 mg oxycodone and naloxone hydrochloride dihydrate, equivalent to 5.0 mg naloxone hydrochloride or 4.5 mg naloxone.

20 mg/10 mg prolonged-release tablets
Each prolonged-release tablet contains 20 mg oxycodone hydrochloride, equivalent to 18.0 mg oxycodone and naloxone hydrochloride dihydrate, equivalent to 10.0 mg naloxone hydrochloride or 9.0 mg naloxone.

40 mg/20 mg prolonged-release tablets
Each prolonged-release tablet contains 40 mg oxycodone hydrochloride, equivalent to 36.0 mg oxycodone and naloxone hydrochloride dihydrate, equivalent to 20.0 mg naloxone hydrochloride or 18.0 mg naloxone.

The other ingredients are:

5 mg/2.5 mg prolonged-release tablets
Tablet core: Microcrystalline cellulose, lactose monohydrate, ammonio methacrylate copolymer, povidone, talc, triacetin, stearyl alcohol, magnesium stearate, anhydrous colloidal silica.
Tablet coat: Hypromellose, macrogol, talc, titanium dioxide (E171), Brilliant Blue FCF (E133).

10 mg/5 mg prolonged-release tablets
Tablet core: Microcrystalline cellulose, lactose monohydrate, ammonio methacrylate copolymer, povidone, talc, triacetin, stearyl alcohol, magnesium stearate, anhydrous colloidal silica.
Tablet coat: Hypromellose, macrogol, talc, titanium dioxide (E171).

20 mg/10 mg prolonged-release tablets
Tablet core: Microcrystalline cellulose, ammonio methacrylate copolymer, povidone, talc, triacetin, stearyl alcohol, magnesium stearate, anhydrous colloidal silica.
Tablet coat: Hypromellose, macrogol, talc, titanium dioxide (E171), red iron oxide (E172).

40 mg/20 mg prolonged-release tablets
Tablet core: Microcrystalline cellulose, ammonio methacrylate copolymer, povidone, talc, triacetin, stearyl alcohol, magnesium stearate, anhydrous colloidal silica.
Tablet coat: Hypromellose, macrogol, talc, titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172).

What Enolwen looks like and contents of the pack

5 mg/2.5 mg prolonged-release tablets
Light blue, round, convex, blue film-coated tablets with a diameter of 7.2 mm.

10 mg/5 mg prolonged-release tablets
White to off-white, oval, convex, film-coated tablets with a length of 13.2 mm.

20 mg/10 mg prolonged-release tablets
Pink, oval, convex, film-coated tablets with a length of 10.2 mm.

40 mg/20 mg prolonged-release tablets
Light orange to ochre, oval, convex, film-coated tablets with a length of 13.2 mm.

5 mg/2.5 mg and 10 mg/5 mg prolonged-release tablets:
The prolonged-released tablets are available in child-resistant perforated unit dose peel-off PVC/PVDC/PVC-Alu blisters.
Pack sizes are 10 x 1, 20 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1, 98 x 1 and 100 x 1.

Or HDPE bottles:
Pack sizes are 20, 50 and 100.

20 mg/10 mg and 40 mg/20 mg prolonged-release tablets:
The prolonged-released tablets are available in child-resistant perforated unit dose peel-off PVC/PVDC/PVC-Alu blisters.
Pack sizes are 10 x 1, 20 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1, 98 x 1 and 100 x 1.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:	Manufacturer:
<to be completed nationally>	Luye Pharma AG Am Windfeld 35 83714 Miesbach Germany Tel.: +49 8025 2867 0 Fax: +49 8025 2867 28 E-mail: info@luyepharma.eu

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