



### Withdrawal symptoms when stopping Matrifen

Do not suddenly stop taking this medicine. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating may occur. If you want to stop taking this medicine, talk to your doctor first. Your doctor will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum.

### Other medicines and Matrifen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines. You should also tell your pharmacist that you are using Matrifen if you buy any medicines from your pharmacy. Your doctor will know which medicines are safe to take with Matrifen. You may need to be closely monitored if you are taking some of the types of medicines listed below or if you stop taking some of the types of medicines listed below, as this may affect the strength of Matrifen you need.

In particular, tell your doctor or pharmacist if you are taking:

- Other medicines for pain, such as other opioid painkillers (such as buprenorphine, nalbuphine or pentazocine) and some pain killers for nerve pain (gabapentin and pregabalin).
- Medicines for helping you sleep (such as temazepam, zaleplon or zolpidem).
- Medicines to help you calm down (tranquillisers, such as alprazolam, clonazepam, diazepam, hydroxyzine or lorazepam) and medicines for mental conditions (anti-psychotics, such as aripiprazole, haloperidol, olanzapine, risperidone or phenothiazines).
- Medicines for relaxing your muscles (such as cyclobenzaprine or diazepam).
- Some medicines used to treat depression called SSRIs or SNRIs (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline or venlafaxine) – see below for more information.
- Some medicines used to treat depression or Parkinson’s disease called MAOIs (such as isocarboxazid, phenelzine, selegiline or tranylcypromine). You should not take Matrifen within 14 days of stopping these medicines – see below for more information.
- Some antihistamines, especially ones that make you sleepy (such as chlorpheniramine, clemastine, cyproheptadine, diphenhydramine or hydroxyzine).
- Some antibiotics used to treat infection (such as erythromycin or clarithromycin).
- Medicines used to treat fungal infection (such as itraconazole, ketoconazole, fluconazole or voriconazole).
- Medicines used to treat HIV infection (such as ritonavir).
- Medicines used to treat an irregular heartbeat (such as amiodarone, diltiazem or verapamil).
- Medicines to treat tuberculosis (such as rifampicin).
- Some medicines used to treat epilepsy (such as carbamazepine, phenobarbital or phenytoin).
- Some medicines used to treat nausea or motion sickness (such as phenothiazines).
- Some medicines used to treat heartburn or ulcers (such as cimetidine).
- Some medicines used to treat angina (chest pain) or high blood pressure (such as nicardipine).
- Some medicines used to treat cancer of the blood (such as idelalisib).

### Matrifen with antidepressants

The risk of side effects increases if you are taking medicines such as certain antidepressants. Matrifen may interact with these medicines and you may experience changes to mental status such as feeling agitated, seeing, feeling, hearing, or smelling things that are not there (hallucinations) and other effects such as changing blood pressure, fast heart beat, high body temperature, overactive reflexes, lack of coordination, muscle stiffness, nausea, vomiting and diarrhoea (these may be signs of Serotonin Syndrome). If used together, your doctor may want to closely monitor you for such side effects in particular when starting treatment or when the dose of your medicine is changed.

### Use with central nervous system depressants, including alcohol and some narcotic drugs

Concomitant use of Matrifen 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 Matrifen 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.

### Operations

If you think that you are going to receive anaesthesia tell your doctor or dentist that you are using Matrifen.

### Matrifen and alcohol

Do not drink alcohol while using Matrifen unless you have talked to your doctor first.

Matrifen can make you drowsy or breathe more slowly. Drinking alcohol may make these effects worse.

### 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 using this medicine.

Matrifen should not be used during pregnancy unless you have discussed this with your doctor.

Matrifen should not be used during childbirth as the medication can affect the breathing of the newborn child.

Prolonged use of Matrifen during pregnancy can cause withdrawal symptoms (such as high-pitched cry, jitteriness, fits, poor feeding and diarrhoea) in your newborn baby that can be life threatening if not recognised and treated. Talk to a doctor immediately if you think your baby may have withdrawal symptoms.

Do not use Matrifen if you are breast-feeding. You should not breastfeed for 3 days after removing your Matrifen patch. This is because the medicine may pass into breast milk.

### Driving and using machines

Matrifen can affect your ability to drive and use machines or tools as it may make you sleepy or dizzy. If this happens, do not drive or use any tools or machines.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely.

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

## 3. How to use Matrifen

Before starting treatment and regularly during treatment, your doctor will also discuss with you what you may expect from using Matrifen when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2, withdrawal symptoms when stopping Matrifen.

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

Your doctor will decide which strength of Matrifen is most suitable for you, taking into account the severity of your pain, your general condition and type of pain treatment that you have received so far.

### Using and changing the patches

- There is enough medicine in each patch to last **3 days (72 hours)**.
- You should change your patch every third day, unless your doctor has told you differently.
- Always remove the old patch **before** applying a new one.
- Always change your patch at the **same time** of day every 3 days (72 hours).
- If you are using more than one patch, change all your patches at the same time.
- Make a note of the day, date and time you apply a patch, to remind you when you need to change your patch.
- The following table shows you when to change your patch:

Apply your patch on	Change your patch on
Monday	➡ Thursday
Tuesday	➡ Friday
Wednesday	➡ Saturday
Thursday	➡ Sunday
Friday	➡ Monday
Saturday	➡ Tuesday
Sunday	➡ Wednesday

### Where to apply the patch

#### Adults

- Apply the patch on a flat part of your upper body or arm (not over a joint).

#### Children

- Always apply the patch to the upper back to make it difficult for your child to reach it or take it off.
- Every so often check that the patch remains stuck to the skin.
- It is important that your child does not remove the patch and put it in their mouth as this could be life threatening or even fatal.
- Watch your child very closely for 48 hours after:
  - The first patch has been put on
  - A higher dose patch has been put on
- It may take some time for the patch to have its maximum effect. Therefore, your child might need to use other painkillers as well until the patches become effective. Your doctor will talk to you about this.

#### Adults and Children:

#### Do not apply the patch on

- The same place twice in a row.
- Areas that you move a lot (joints), skin that is irritated or with cuts.
- Skin that is very hairy. If there is hair, do not shave it (shaving irritates the skin). Instead, clip the hair as close to the skin as possible.

### Putting a patch on

#### Step 1: Preparing the skin

- Make sure your skin is completely dry, clean and cool before you put the patch on
- If you need to clean the skin, just use cold water
- Do not use soap or any other cleansers, creams, moisturisers, oils or talc before applying the patch
- Do not stick a patch on straight after a hot bath or shower

#### Step 2: Open the sachet

- Each patch is sealed in its own sachet
- Tear or cut open the sachet at the notch, shown by the arrow
- Gently tear or cut off the edge of the sachet completely (if you use scissors, cut close to the sealed edge of the sachet to avoid damaging the patch)
- Grasp both sides of the opened sachet and pull apart



- Take the patch out and use straight away
- Keep the empty sachet to dispose of the used patch later
- Use each patch once only
- Do not take the patch out of its sachet until you are ready to use it
- Inspect the patch for any damage
- Do not use the patch if it has been divided, cut or looks damaged
- Never divide or cut the patch

#### Step 3: Peel and press

- Make sure that the patch will be covered by loose clothing and not stuck under a tight or elasticated band
- Carefully peel one half of the shiny plastic backing away from the centre of the patch. Try not to touch the sticky side of the patch
- Press this sticky part of the patch onto the skin
- Remove the other part of the backing and press the whole patch onto the skin with the palm of your hand
- Hold for at least 30 seconds. Make sure it sticks well, especially the edges

#### Step 4: Disposing of the patch

- As soon as you take a patch off, fold it firmly in half so that the sticky side sticks to itself.
- Put it back in its original sachet and dispose of the sachet as instructed by your pharmacist
- Keep used patches out of sight and reach of children – even used patches contain some medicine which may harm children and may even be fatal

#### Step 5: Wash

- Always wash your hands after you have handled the patch using clean water only

#### More about using Matrifen

#### Everyday activities while using the patches

- The patches are waterproof
- You can shower or bathe while wearing a patch, but do not scrub the patch itself
- If your doctor agrees, you can exercise or play sport while wearing the patch
- You can also swim while wearing the patch, but:
  - Don't use hot whirlpool spa baths
  - Don't put a tight or elasticated band over the patch

- While you are wearing the patch do not expose it to direct heat such as heating pads, electric blankets, hot-water bottles, heated water beds, heat or tanning lamps. Do not sunbathe, have long hot baths or saunas. If you do, you may increase the amount of medicine you get from the patch.

#### How quickly will the patches work?

- It may take some time for your first patch to have its maximum effect
- Your doctor may give you other painkillers as well for the first day or so
- After this, the patch should help to relieve pain continuously so that you can stop taking other painkillers. However, your doctor may still prescribe extra painkillers from time to time.

#### How long will you use the patches for?

- Matrifen patches are for long-term pain. Your doctor will be able to tell you how long you can expect to use the patches.

#### If your pain gets worse

- If your pain suddenly gets worse after placing your last patch, you should check your patch. If it is no longer sticking well or has fallen off you should replace the patch (*See also section If a patch falls off*).
- If your pain gets worse over time while you are using these patches, your doctor may try a higher strength patch, or give you additional painkillers (or both).
- If increasing the strength of the patch does not help, your doctor may decide to stop the use of the patches.

#### If you use too many patches or the wrong strength patch

If you have stuck on too many patches or the wrong strength patch, take the patches off and contact a doctor straight away.

Signs of overdose include trouble breathing or shallow breathing, tiredness, extreme sleepiness, being unable to think clearly, walk or talk normally and feeling faint, dizzy or confused. An overdose may also result in a brain disorder known as toxic leukoencephalopathy.

#### If you forget to change your patch

- If you forget, change your patch as soon as you remember and make note of the day and time. Change the patch again after **3 days (72 hours)** as usual.
- If you are very late changing your patch, you should talk to your doctor because you might need some extra painkillers, but do **not** apply an extra patch.

#### If a patch falls off

- If a patch falls off before it needs changing, stick a new one on straight away and make note of the day and time. Use a new area of skin on:
  - Your upper body or arm
  - Your child’s upper back
- Let your doctor know this has happened and leave the patch on for another **3 days (72 hours)** or as directed by your doctor, before changing the new patch as usual
- If your patches keep falling off, talk to your doctor, pharmacist or nurse

#### If you want to stop using the patches

- Do not suddenly stop taking this medicine. If you want to stop taking this medicine, talk to your doctor first. Your doctor will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. See also section 2 ‘*Withdrawal symptoms when stopping Matrifen*’
- If you stop using the patches, don’t start again without asking your doctor first. You might need a different patch strength when you restart.

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.

**If you or your partner, or carer, notice any of the following about the person wearing the patch, take the patch off and call a doctor, or go to your nearest hospital, straight away. You may need urgent medical treatment.**

- Feeling unusually drowsy, breathing that is more slow or shallow than expected
  - Follow the advice above and keep the person who was wearing the patch moving and talking as much as possible. Very rarely these breathing difficulties can be life-threatening or even fatal, especially in people who have not used strong opioid painkillers (like Matrifen or morphine) before. (Uncommon, this may affect up to 1 in 100 people)
- Sudden swelling of the face or throat, severe irritation, reddening or blistering of your skin.
  - These may be signs of a severe allergic reaction. (Frequency cannot be estimated from the available data)
- Fits (seizures). (Uncommon, this may affect up to 1 in 100 people)
- Reduced consciousness or loss of consciousness. (Uncommon, these may affect up to 1 in 100 people).

#### The following side effects have also been reported

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

- Nausea, vomiting, constipation
- Feeling sleepy (somnolence)
- Feeling dizzy
- Headache

#### Common (may affect up to 1 in 10 people)

- Allergic reaction
- Loss of appetite
- Difficulty sleeping
- Depression
- Feeling anxious or confused
- Seeing, feeling, hearing, or smelling things that are not there (hallucinations)
- Muscle tremors or spasms
- Unusual feeling in the skin, such as tingling or crawling feelings (paraesthesia)
- Spinning sensation (vertigo)
- Heartbeat feels fast or uneven (palpitations, tachycardia)
- High blood pressure
- Being short of breath (dyspnoea)
- Diarrhoea
- Dry mouth
- Stomach pain or indigestion
- Excessive sweating
- Itching, skin rash or redness of the skin
- Being unable to pass urine or empty bladder completely
- Feeling very tired, weak or generally unwell
- Feeling cold
- Swollen hands, ankles or feet (peripheral oedema)