Patient Information Leaflet for SKUDEXA

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

SKUDEXA film-coated tablets

Tramadol hydrochloride / Dexketoprofen

Sugar free.

Read all of this leaflet carefully before you start taking SKUDEXA.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- SKUDEXA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SKUDEXA is and what it is used for

SKUDEXA is used for the symptomatic short term-treatment of moderate to severe acute pain in adults.

SKUDEXA contains the active substances tramadol hydrochloride and dexketoprofen.

Tramadol hydrochloride is a pain killer belonging to a group of medicines called opioids that act on the central nervous system. It relieves pain by acting on specific nerve cells of the brain and spinal cord.

Dexketoprofen is a pain killer and it belongs to a group of medicines called nonsteroidal anti-inflammatory medicines.

2. What you need to know before you take SKUDEXA

Do not take SKUDEXA

- If you are allergic to dexketoprofen, tramadol hydrochloride or any of the other ingredients of SKUDEXA (listed in section 6).
- If you are allergic to acetylsalicylic acid or to other nonsteroidal anti-inflammatory medicines.
- If you have asthma or have suffered attacks of asthma, acute allergic rhinitis (a short period of inflamed lining of the nose), nasal polyps (lumps within the nose due to allergy), urticaria (skin rash), angioedema (swollen face, eyes, lips, or tongue, or respiratory distress) or wheezing in the chest after taking acetylsalicylic acid or other nonsteroidal anti-inflammatory medicines.
- If you have suffered from photoallergic or phototoxic reactions (a particular form of reddening and/or blistering of the skin exposed to sunlight) while taking ketoprofen (a nonsteroidal anti-inflammatory medicine) or fibrates (medicines used to lower the level of fats in the blood).
- If you have a peptic ulcer, stomach or bowel bleeding or if you have suffered in the past from stomach or bowel bleeding, ulceration or perforation, including that due to previous use of nonsteroidal anti-inflammatory medicines.
- If you have chronic digestive problems (e.g. indigestion, heartburn).
- If you have suffered in the past from stomach or bowel bleeding or perforation, due to previous use of nonsteroidal anti-inflammatory medicines used for pain.
- If you have bowel disease with chronic inflammation (Crohn’s disease or ulcerative colitis).
- If you have serious heart failure, moderate or serious kidney problems or serious liver problems.
- If you have a bleeding disorder or a blood clotting disorder.

- If you are severely dehydrated (have lost a lot of body fluids) due to vomiting, diarrhoea or insufficient intake of fluids.
- If you have acute poisoning with alcohol, sleeping pills, pain relievers, or medicines that affect mood and emotions.
- If you are also taking monoamine oxidase inhibitors (MAOIs) (certain medicines used for the treatment of depression) or have taken them in the last 14 days before treatment with this medicine (see “Other medicines and SKUDEXA”).
- If you have epilepsy of suffer from fits, because the risk of a fit may increase.
- If you are breathing with difficulty.
- If you have a head injury or have a decreased level of consciousness.
- If you are pregnant or are breastfeeding your baby.

Warnings and precautions

Take special care with SKUDEXA:

- If you suffer from allergy, or if you have had allergy problems in the past.
- If you have kidney, liver or heart problems (hypertension and/or heart failure) as well as fluid retention or have suffered from any of these problems in the past.
- If you are taking diuretics.
- If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist. Medicines such as SKUDEXA may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- If you are an elderly person: you may be more likely to suffer from side effects (see section 4). If any of these occur, consult your doctor immediately.
- If you are a woman with fertility problems: SKUDEXA may impair your fertility, therefore you should not take it if you are planning to become pregnant or you are doing fertility tests.

- If you suffer from a disorder in the formation of blood and blood cells.
- If you have systemic lupus erythematosus or mixed connective tissue disease (immune system disorders that affect connective tissue).
- If you have suffered in the past from a chronic inflammatory disease of the bowel (ulcerative colitis, Crohn's disease).
- If you have or have suffered in the past from other stomach or bowel problems.
- If you have varicella (chickenpox), since exceptionally nonsteroidal anti-inflammatory medicines could worsen the infection.
- If you are taking other medicines that increase the risk of peptic ulcer or bleeding, e.g. oral steroids, some antidepressants (selective serotonin reuptake inhibitors), medicines that prevent blood clots such as aspirin or anticoagulants such as warfarin. In such cases, consult your doctor before taking SKUDEXA: he/she may want you to take an additional medicine to protect your stomach.
- If you suffer from asthma combined with chronic rhinitis, chronic sinusitis, and/or nasal polyposis as you have a higher risk of allergy to acetylsalicylic acid and/or nonsteroidal anti-inflammatory medicines than the rest of the population. Administration of SKUDEXA can cause asthma attacks or bronchospasm, particularly in patients allergic to acetylsalicylic acid or nonsteroidal anti-inflammatory medicines.
- If you are taking other medicines containing the same active substances in this medicine, do not exceed the maximum daily doses of dexketoprofen or tramadol.
- If you think that you are addicted to other pain relievers (opioids).
- If you have consciousness disorders (if you feel that you are going to faint).
- If you are in a state of shock (cold sweat may be a sign of this).
- If you have increased pressure in the brain (possibly after a head injury or brain disease).
- If you have difficulty in breathing.
- If you have porphyria.

Tramadol may lead to physical and psychological addiction. The risk of addiction may increase if

you or a family member previously had mental health problems, characterised by a persistently low or depressed mood (major depression), feeling of fear or worry (anxiety), or misused alcohol or drugs. When SKUDEXA is taken for a long time, its effect may decrease, so that higher doses have to be taken (tolerance development). In patients with a tendency to abuse medicines or who are dependent on medicines, treatment with SKUDEXA should only be carried out for short periods and under strict medical supervision.

Tell your doctor if any of these problems occurs during SKUDEXA treatment or if they applied in the past.

Children and adolescents

SKUDEXA has not been studied in children and adolescents. Therefore, safety and efficacy have not been established and SKUDEXA should not be used in children and adolescents.

Other medicines and SKUDEXA

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not use the following medicines if you take SKUDEXA:

- Acetylsalicylic acid, corticosteroids or other anti-inflammatory drugs.
- Warfarin, heparin or other medicines used to prevent blood clots.
- Lithium, used to treat certain mood disorders.
- Methotrexate (anticancer medicine or immunosuppressant), used at high doses of 15 mg/week.
- Hydantoins and phenytoin, used for epilepsy.
- Sulfamethoxazole, used for bacterial infections.
- Monoamine oxidase inhibitors (MAOIs) (medicines for the treatment of depression).

Tell your doctor or pharmacist before you take SKUDEXA if you use:

- ACE inhibitors, diuretics and angiotensin II antagonists, used for high blood pressure and

heart problems.

- Pentoxifylline, used to treat chronic venous ulcers.
- Zidovudine, used to treat viral infections.
- Chlorpropamide and glibenclamide, used for diabetes.
- Aminoglycosides antibiotics, used to treat bacterial infections.
- Quinolone antibiotics (e.g. ciprofloxacin, levofloxacin) used for bacterial infections.
- Ciclosporin or tacrolimus, used to treat immune system diseases and in organ transplant.
- Streptokinase and other thrombolytic or fibrinolytic medicines, i.e. medicines used to break-up blood clots.
- Probenecid, used in gout.
- Digoxin, used to treat chronic heart failure.
- Mifepristone, used as an abortifacient (to terminate a pregnancy).
- Antidepressants of the selective serotonin reuptake inhibitors type (SSRIs).
- Antiplatelet medicines used to reduce platelet aggregation and the formation of blood clots.
- Tenofovir, deferasirox, pemetrexed.

The pain-relieving effect of tramadol may be reduced, and the length of time it acts may be shortened, if you also take medicines containing:

- Carbamazepine (for epileptic fits).
- Buprenorphine, nalbuphine, or pentazocine (pain relievers).
- Ondansetron (prevents nausea).

The risk of side effects increases:

- If you take tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), or alcohol while you are taking SKUDEXA. You might feel drowsier or feel that you might faint. If this happens tell your doctor.
- If you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take SKUDEXA

at the same time. Your doctor will tell you whether SKUDEXA is suitable for you.

- If you are taking certain antidepressants. SKUDEXA may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles (including the muscles that control movement of the eye), agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 °C**.**
- If you take anticoagulants (medicines for blood thinning), e.g. warfarin, together with this medicine. The effect of these medicines on blood clotting may be affected and bleeding may occur.

SKUDEXA with alcohol

Do not drink alcohol during treatment with SKUDEXA as it may increase the effect of the medicine.

For the instruction how to take SKUDEXA see section 3.

Pregnancy and breastfeeding

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

The use of SKUDEXA is contraindicated in pregnancy as well as during breastfeeding.

Driving and using machines

SKUDEXA may affect your ability to drive a vehicle and operate machines, due to the possibility of dizziness, blurred vision or drowsiness as side effects of treatment. This applies particularly when SKUDEXA is taken with medicines that affect mood and emotions, or alcohol. If you are affected, do not drive a vehicle or use machines until the symptoms wear off.

3. How to take SKUDEXA

Always take SKUDEXA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of SKUDEXA is too strong or too weak, tell your doctor or

pharmacist.

The dose of SKUDEXA that you need depends on the type, severity and duration of your pain.

Your doctor will tell you how many tablets you must take daily, and for how long.

The recommended dose is generally one (1) tablet (corresponding to 75 mg of tramadol hydrochloride and 25 mg of dexketoprofen) every 8 hours, with no more than three (3) tablets daily (corresponding to 225 mg of tramadol hydrochloride and 75 mg of dexketoprofen) and not exceeding 5 days of treatment.

Use in children and adolescents

SKUDEXA is not suitable for children and adolescents (under the age of 18 years).

Elderly patients

If you are aged 75 years or over, your doctor may recommend prolonging the dosage interval because your body may handle SKUDEXA more slowly.

Severe liver or kidney disease/dialysis patients

Patients with severe liver and/or kidney disease should not take SKUDEXA.

In case of renal dysfunction, if in your case the insufficiency is mild, your doctor may recommend prolonging the dosage interval.

In case of hepatic dysfunction, if in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

Swallow the tablet with a sufficient amount of fluid (preferably with a glass of water). Food delays the absorption of SKUDEXA, so for a faster effect take the tablet at least 30 minutes before meals.

The score line is to help you break the tablet if you have difficulty swallowing it whole.

If you take more SKUDEXA than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available,

contact the nearest hospital or poison centre. Take any tablets that are left, including the carton, so that the hospital staff can easily tell what you have taken.

The symptoms of an overdose of this medicine are:

- vomiting, loss of appetite, stomach pain, drowsiness, dizziness/spinning sensation, disorientation, headache (for dexketoprofen).
- contraction of the pupil, vomiting, heart failure, loss of consciousness, convulsions and difficulty in breathing (for tramadol).

If you forget to take SKUDEXA

Do not take a double dose to make up for a forgotten tablet. Take the next regular dose when it is due (according to section 3 “How to take SKUDEXA”).

If you stop taking SKUDEXA

Generally, there will be no after-effects when treatment with SKUDEXA is stopped within the specified maximum duration of use, 5 days. However, patients who have exceeded the dose recommendations for taking SKUDEXA tablets may feel unwell if they stop taking them abruptly. They may feel agitated, anxious, nervous or shaky, be confused, hyperactive, have difficulty sleeping and have stomach or bowel disorders. People may get panic attacks, hallucinations, delusions, paranoia or feel a loss of identity. They may experience unusual perceptions such as itching, tingling and numbness, and ringing in the ears (tinnitus). Further unusual symptoms, i.e. confusion, delusions, feeling as though you are detached from yourself (depersonalisation), and change in perception of reality (derealisation) and delusion of persecution (paranoia) have been seen. If you experience any of these complaints after stopping SKUDEXA, please consult your doctor.

4. Possible side effects

SKUDEXA can have side effects.

Not all side effects reported for SKUDEXA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SKUDEXA, please consult your health care provider for advice.

If any of the following happens, stop taking SKUDEXA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Anaphylactic reaction (hypersensitive reaction which may also lead to fainting).
- Face swelling or swelling of the lips and throat (angioedema).
- Breathlessness due to narrowing of the airways (bronchospasm), shortness of breath.

These are all very serious side effects. If you have them, you may have had a serious reaction to SKUDEXA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea/feeling sick
- vomiting
- stomach
- diarrhoea
- digestive problems (dyspepsia)
- constipation
- dry mouth
- headaches
- drowsiness, fatigue

Less frequent side effects:

- effects on the heart and blood circulation (pounding of the heart, fast heartbeat, feeling faint or collapse), low blood pressure. These adverse effects may occur particularly when patients are in an upright position or under physical strain.

- high or very high blood pressure
- swelling in the voice-box (laryngeal oedema)
- reduced potassium in the blood
- psychotic disorder
- swelling next to the eye
- shallow or slow breathing
- discomfort, abnormal feeling
- blood in urine
- spinning sensation
- sleeplessness or difficulty falling asleep
- nervousness/anxiety
- flushing
- flatulence
- tiredness
- pain
- feeling feverish and shivering, generally feeling unwell
- abnormal blood tests
- urge to vomit (retching)
- feeling of pressure in the stomach, bloating
- inflammation of the stomach
- skin reactions (e.g. itching, rash)
- facial swelling
- peptic ulcer, peptic ulcer perforation or bleeding, which may be seen as vomiting blood or black stools
- prostate problems
- liver inflammation (hepatitis), liver damage
- acute kidney failure
- slow heartbeat

- epileptic fits
- transient loss of consciousness (syncope)
- hallucinations
- water retention or swollen ankles
- loss of appetite, changes in appetite
- acne
- back pain
- passing urine frequently, or less than normal, with difficulty or pain
- menstrual disorders
- abnormal sensations (e.g. itching, tingling, numbness)
- trembling, muscle twitches, uncoordinated movement, weak muscles
- confusion
- sleep disorders and nightmares
- disturbed perception
- blurred vision, contraction of the pupil
- shortness of breath
- stomach pain, including inflammation of the pancreas
- kidney problems
- reduced white blood cell count (neutropenia)
- fewer platelets in the blood (thrombocytopenia)
- open sores on skin, mouth, eyes and genital areas (Stevens-Johnson syndrome and toxic epidermal necrolysis)
- breathlessness due to narrowing of the airways
- ringing in the ears (tinnitus)
- sensitivity to light

Side effects with the frequency unknown:

- speech disorders

- extreme pupil dilatation
- decrease in blood sugar levels.

Psychological side effects may occur after treatment with SKUDEXA. Their intensity and nature may vary (according to the patient's personality and length of therapy):

- change in mood (mostly high spirits, occasionally irritation)
- changes in activity (slowing down but sometimes an increase in activity)
- being less aware
- less able to make decisions, which may lead to errors in judgement.

If SKUDEXA is taken over a long period of time dependence may occur. When treatment is stopped abruptly signs of withdrawal may appear (see "If you stop taking SKUDEXA").

Epileptic fits have occurred especially at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits.

Tell your doctor immediately if you notice any stomach/bowel side effects at the start of treatment (e.g. stomach pain, heartburn or bleeding), if you have previously suffered from any such side effects due to long-term use of anti-inflammatory drugs, and especially if you are an elderly person.

In patients with immune system disorders that affect connective tissue (systemic lupus erythematosus or mixed connective tissue disease), anti-inflammatory medicines may rarely cause fever, headache and neck stiffness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your health care provider. This includes any possible side effects not

listed in this leaflet. You can also report side effects via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

5. How to store SKUDEXA

- Store at or below 25 °C.
- Store in the original package in order to protect from light.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SKUDEXA contains

The active substances are tramadol hydrochloride and dexketoprofen. Each tablet contains 75 mg of tramadol hydrochloride and 25 mg dexketoprofen.

The other ingredients are:

Tablet core: microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, sodium stearyl fumarate, anhydrous silica colloidal.

Film-coating: polyvinyl alcohol, titanium dioxide (E171), Macrogol/PEG 3350, talc.

What SKUDEXA looks like and contents of the pack

Almost white to slightly yellow, oblong, film-coated tablets with a break-mark on one side and a debossed “M” on the other side.

The film-coated tablets are provided in PVC/PVDC/aluminium blisters.

Pack sizes: 15 or 20 film-coated tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Request via the email address: info@menarini.co.za