PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

UNIFLEX, Tablets
Paracetamol 450 mg
Orphenadrine citrate 35 mg
Sugar free

Read all of this leaflet carefully because it contains important information for you.

UNIFLEX is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use UNIFLEX carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share UNIFLEX with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet:

1. What UNIFLEX is and what it is used for

UNIFLEX contains paracetamol 450 mg and orphenadrine citrate 35 mg, which belongs to a group of medicine referred to as analgesic combinations.

UNIFLEX is used for generalised pain and the relief of muscle spasm associated with acute painful musculo-skeletal conditions.

2. What you need to know before you take UNIFLEX tablets

Do not take UNIFLEX:

If you are hypersensitive (allergic) to paracetamol and orphenadrine or any of the other ingredients of UNIFLEX (listed in section 6)

If you suffer from the following:

- severe liver function
- enlarged prostate
- achalasia (a failure of smooth muscle fibres to relax, which can cause the lower oesophageal sphincter to remain closed)
- bladder neck obstruction
- glaucoma (a condition in which the pressure of fluid in the eye is high. This can damage your eye's optic nerve)
- myasthenia gravis (a disorder causing extreme muscle weakness and can impact a person's ability to see, smile, walk, talk and breathe)
- peptic ulcer (a lesion in the lining (mucosa) of the digestive tract, typically in the stomach or duodenum)
- stenosing and pyloric or duodenal obstruction
- porphyria (a group of diseases in which substances called porphyrins build up, negatively affecting the skin or nervous system)

Warnings and precautions

This product contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Special care should be taken with UNIFLEX:

- If you suffer from liver or kidney disease.
- If you are taking other central nervous system depression-producing medication or you are on anticholinergics or medication with anticholinergic properties.
- Use with caution in patients with cardiac disease (heart disease).
- Dosages in excess of those recommended may cause severe liver damage.
- Do not use continuously for more than 10 days without consulting your doctor.
- Serious skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), eosinophilia and systemic (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE), have been reported in patients receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using UNIFLEX immediately and contact your doctor (see Section 4).

Children and adolescents

The use of UNIFLEX in children and adolescents has not been established.

Other Medicines and UNIFLEX

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

Orphenadrine may increase central nervous system depression if taken concurrently with alcohol or central nervous system depressants. Anticholinergic effects may be intensified if orphenadrine is taken concurrently with anticholinergics or medication with anticholinergic effects.

Prolonged use of paracetamol and a salicylate significantly increases the risk of kidney damage. Use of paracetamol with anticoagulants (medicines used to prevent blood clots) coumarin-or indandione-derivative may increase their effects.

Sleeping medication taken together with paracetamol decreases the therapeutic effect of paracetamol.

Risk of hepatotoxicity with single toxic doses or prolonged use of high doses of paracetamol may be increased in alcoholics or in patients taking other hepatotoxic medications or hepatic enzyme inducers.

UNIFLEX with food and drinks
No known interactions with food and drink.

Pregnancy, breastfeeding and fertility
The safety of using **UNIFLEX** during pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machines
This medicine may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

3. How to take UNIFLEX

Do not share medicines prescribed for you with any other person.
Always take UNIFLEX exactly as described in this leaflet or as your doctor, or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Adults: 2 tablets 3 times a day.

Do not exceed the recommended dosage.

If you take more UNIFLEX than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
The most likely symptoms of overdosage are stomach pain, nausea, vomiting and insomnia.

If you forget to take UNIFLEX

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

4. Possible side effects

UNIFLEX can have side effects.

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

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

Frequency not known (cannot be estimated from the available data):

• Mouth ulcers, cold sores and ulcers or soreness of your tongue

• Skin lumps or hives (raised, red or white, itchy patches of skin)

• Blisters on your skin or inside your mouth, nose, vagina or bottom

• The appearance of a rash or sunburn when you have been outside (even on a cloudy day)

• swelling of the eyelids, face, tongue or lips

• severe dizziness

• difficulty in breathing

• Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals), stop giving UNIFLEX immediately and contact your doctor (see Section 2)

Other side effects include:

Blood disorders:

Thrombocytopenia (decreased number of blood platelets), leucopenia (decreased number of white blood cells), pancytopenia (decreased number of cell elements in the blood), neutropenia (decreased number of neutrophilic leukocytes cells in the blood), agranulocytosis (low number of granulocytes, a type of white blood cell) and anaemia (low number of red blood cells), anaemia (low number of red blood cells).

Stomach and bowel disorders:
Pancreatitis (inflammation of the pancreas). Dryness of the mouth with difficulty in swallowing and talking, thirst, constipation and occasionally vomiting.

Skin disorders:
Skin rashes, dryness of the skin and other allergic reactions.

Liver disorders:
Hepatitis (inflammation of the liver)

Kidney disorders:
Renal colic (pain caused by a urinary tract stone), renal failure and sterile pyuria (urine which contains white blood cells) and difficulty in urination.

Eye disorders:
Dilation of the pupils with loss of accommodation and photophobia (extreme sensitivity to light)

Heart disorders:
Transient bradycardia (slowing of the heart beat) followed by tachycardia (fast heart beat) with palpitations and arrhythmias (abnormal rhythm of the heart)

Lung disorders:
Bronchial secretion

Nervous system disorders:
Confusion, dizziness and walking unsteadily.

Blood vessels disorders:
Flushing (sudden increase in flow)

Psychiatric disorders:
Insomnia (inability to sleep)

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 doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of UNIFLEX. You may also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

5. How to store UNIFLEX

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Store at or below 25 °C. Protect from light.
Store in the original container
Keep the container tightly closed.
Do not store in a bathroom.
Do not use after the expiry date stated on the label/carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What UNIFLEX contains:

UNIFLEX contains the active ingredients paracetamol and orphenadrine citrate.

Each Tablet contains:

450 mg of paracetamol and 35 mg of orphenadrine citrate.

The other ingredients are:

Colloidal anhydrous silica, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, sodium starch, glycolate and stearic acid Sugar free.

What UNIFLEX looks like and contents of the pack

White, circular, biconvex tablets with a breaker on one face.

Cartons containing polyvinyl chloride (PVC) / aluminium blister packs of 20's, 50's, 100's and 120 tablets. Polypropylene securitainers with low-density polyethylene (LDPE) closures containing 50 and 100 tablets. White screw type HDPE container with white high-density polyethylene (HDPE) screw cap containing 120 tablets.

Holder of Certificate of Registration

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Marketed by:

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