

1.3
PRODUCT INFORMATION

1.3.1
Summary Of Product Characteristics (SPC)

1.3.1 Product information for health professionals

1. NAME OF THE MEDICINAL PRODUCT

1.1 Invented Name of the Medicinal Product

REALFLEX

Phenyramidol HCL 400mg Tablets

1.2 Strength

400mg

1.3 Pharmaceutical Form

Oral dosage form

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each filmcoated tablets Contains:

Phenyramidol HCl400 mg.

Excipientsq.s.

Colour: Titanium dioxide, Lake quinolone yellow, Yellow iron oxide

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

REALFLEX tablet indicated for the treatment of neck & shoulder pain, painful conditions associated with muscle spasm, chronic back pain, soft tissue pain, painful spasms associated with sports injury, relieves muscle tension and pain and maintains the function of cramped skeletal muscle.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

REALFLEX 1 to 2 tablets of 400 mg should be swallowed after meals, 2 to 3 times daily for 5 to 7 days, depending on severity of the condition or as directed by the physician.

4.2 CONTRAINDICATIONS

There are no known contraindications recorded with phenyramidol HCl. However, it should not be administered in individuals who are sensitive to any substance in the composition.

4.4 WARNING AND PRECAUTIONS

Administration of REALFLEX results in potentiation of anticoagulant, antidiabetic and anticonvulsant effects of drugs. Administer REALFLEX with caution, in patients on concomitant administration with anticoagulant, antidiabetic and anticonvulsant drugs

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Elevated plasma concentrations of phenytoin are reported in epileptic patients, taking both drugs simultaneously. Phenyramidol HCl is known to inhibit the metabolism of tolbutamide and bishydroxycoumarin, zoxazolamine or pentobarbital.

4.6 PREGNANCY AND LACTATION

PREGNANCY:

It is advisable that REALFLEX should be avoided during pregnancy and lactation.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Being a non-narcotic, non-habituating, non-opiod, analgesic and muscle relaxant, REALFLEX® does not produce drowsiness and hence can be safely administered to ambulatory patients.

4.8 UNDESIRABLE EFFECTS

Brand Name: REALFLEX

Generic Name: Phenyramidol HCL 400mg Tablets

**Module 1
(Administrative File)**

It may cause bloated feeling in the stomach or nausea, burn feeling in tongue or skin exanthema in some hypersensitive patients. However, these are temporary, also numbness, pruritus and rash may occur. Drug should be discontinued when hypersensitivity and rash occur.

4.9 OVERDOSE

No overdosage symptoms have been reported in patients treated with REALFLEX®. A dose of 3200 mg per day has been readily tolerated without any signs of side effects or untoward effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiinflammatory, Analgesic

ATC code: MO3BX30

Mechanism of action:

Phenyramidol HCl interrupts inter-neuronal and polysynaptic reflexes in the spinal cord and brain system, thereby exerts dual action namely skeletal muscle relaxation and analgesia.

5.2 Pharmacokinetic properties

After oral administration, the drug is readily absorbed from the GI tract. Peak plasma concentration is achieved in 40-45 minutes. The elimination half-life is found to be approximately 11 hours. Considerable amount is principally excreted as glucuronide into urine. Small proportions are also excreted in the feces.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development. No carcinogenicity studies have been performed; however, there is no evidence to suggest carcinogenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Microcrystalline cellulose
Maize starch
PVPK-30
Magnesium stearate
Talc
Colloidal silicon dioxide
PEG 6000
Instacoat Universal
Isopropyl alcohol
Methylene chloride

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30°C. Protect from light.

Keep all medicines out of reach of children.

6.5 Nature and contents of container

REALFLEX is available as a Blister of 10 tablets. 3 such blisters packed in a printed carton along with pack insert.

6.6 Special precautions for disposal and other Special handling

None

Brand Name: REALFLEX

Generic Name: Phenyramidol HCL 400mg Tablets

**Module 1
(Administrative File)**

7. Marketed by:

REALS PHARMACEUTICALS LTD.

Plot 1, Junaid Dosunmu Street,
CBD, Alausa, Ikeja, Lagos State,
Nigeria.