REALFLEX®

Phenyreamidol HCL 400mg tablets

Each film coated tablets contains:

Phenyramidol Hcl	400 mg
Excipents	q.s.
Colour:	Titanium Dioxide IP, Lake
Quinoline	Yellow, Yellow Iron Oxide USP

PHARMACOLOGICAL PROPERTIES

The mechanism of the muscle relaxant effect of phenyramidol HCI **(REALFLEX®)** is due to blocking of the interneurons and polysynaptic reflexes. **REALFLEX®** breaks pain strain chain by blocking polysynaptic reflexes in brain and medulla spinalis. In this manner, it relieves muscle tension, and it has a strong analgesic effect on muscle pain. It does not affect monosynaptic reflexes.

PHARMACODYNAMICS

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

PHARMACOKINETICS

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.

THERAPEUTICAL 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.

DOSAGE AND 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.

CONTRAINDICATIONS

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

SPECIAL 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.

Pregnancy and Lactation:

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

Effect 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.

OVERDOSAGE:
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.

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

SIDE EFFECTS:
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.

KEEP MEDICINE OUT OF REACH OF CHILDREN.

STORAGE:
Store in a cool, dry place, protect from light.

Presentation:
Available as Alu-Alu pack of 10 tablets in a carton of 3x10 tablets.

Under license from
FBL Fermenta Biotech Ltd,
DIL Complex, Thane-400 610.