SUMMARY OF PRODUCT CHARACTERISTICS [SmPC]
QUIX TABLET

1. NAME OF THE MEDICINAL PRODUCT

QUIX TABLET

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

COMPOSITION:

Each uncoated Tablet contains:
Bromelain ……40mg
Crystalline Trypsin.... ……1mg
Excipients.....qs

3. PHARMACEUTICAL FORM

Oral solid preparation

4. CLINICAL PARTICULARS

4.1Therapeutic indications

QUIX Tablet is indicated for pain, and inflammation in rheumatic disease (including juvenile idiopathic arthritis) and other musculoskeletal disorders namely acute gout, post-operative pain.

DOSE: ***ADULT***: By mouth, 2 tablets after food every 8 hours.

Special warnings and precautions for use

QUIX Tablet should be avoided in patients with asthma, peptic ulcer, liver or kidney disease, high blood pressure.

QUIX should be given with care to patients with coagulation disorders or with severe hepatic or renal impairment.

QUIX Tablet is contraindicated in severe heart failure. The selective inhibitors of cyclo-oxygenase-2 (celeoxib, etoricoxib and parecoxib) are contraindicated in ischaemic heart disease, cerebrovascular disease, peripheral arterial disease and moderate or severe heart failure. The selective inhibitors of cyclo-oxygenase-2 should be used with caution in patients with a history of cardiac failure, left ventricular

dysfunction, hypertension in patients with oedema for any other reason, and in patients with risk factor for heart disease

4.3Contraindications

4.5 QUIX Tablet is contraindicated in severe heart failure. The selective inhibitors of cyclo-oxygenase-2 (celeoxib, etoricoxib and parecoxib) are contraindicated in ischaemic heart disease, cerebrovascular disease, peripheral arterial disease and moderate or severe heart failure. The selective inhibitors of cyclo-oxygenase-2 should be used with caution in patients with a history of cardiac failure, left ventricular dysfunction, hypertension in patients with oedema for any other reason, and in patients with risk factor for heart disease

4.6 drug interaction

The concurrent administration of NSAIDS and QUIX Tables leads to decrease in the blood concentration of the later ,and an increase in side- effects.

Overdose

In cases of overdosage with QUIX Tablets, management is supportive. Further administration is stopped and activated charcoal is given by mouth to bind the remaining drugs in the gastrointestinal system thereby reducing their absorption. The usual adult dose of activated charcoal is 50g initially then 50g every 4 hours.

Pharmacology and toxicology

Bromelains are a concentrate of proteolytic enzymes derived from the pineapple plant, *Ananas comosus* (*A. sativus*) (Bromeliaceae). They are used as an adjunct in the treatment of soft-tissue inflammation and oedema associated with trauma and surgery. Bromelains have also been given as an aid to digestion, and used in the treatment of partial deep dermal and full thickness burns.

Trypsin is a proteolytic enzyme that has been applied for the debridement of wounds. It has also been taken by mouth, usually with chymotrypsin , and sometimes with antibacterial or other drugs, for its supposed benefit in relieving oedema and inflammation associated with infection or trauma. Trypsin solutions have been inhaled for the liquefaction of viscous sputum, and trypsin is also an ingredient of mixtures intended to relieve various gastrointestinal disorders. Trypsin has been used in oncology in a combination preparation with chymotrypsin and papain.

Pharmacokinetics

Bromelain together with crystalline Trypsin is well absorbed from the gastrointestinal

tract; peak plasma concentrations are reached 3 to 4 hours after an oral dose.

Undesirable effects

Quix Tablets may cause nausea, vomiting, and diarrhoea. Metrorrhagia and menorrhagia have occasionally occurred. Hypersensitivity reactions have been reported and have included skin reactions and asthma.

Bronchial asthma was experienced by 2 patients after exposure to bromelains.[1] Of 6 workers sensitised to papain, 5 showed positive skin tests to bromelains and 2 of them also showed immediate asthmatic reactions after bronchial challenge with bromelains**6.**

PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch

microcrystalline cellulose

polysorbate 80

pregelatinized starch

sodium carboxymethyl starch

magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

3years.

6.4 Special precautions for storage

Store below 30^{o}Cin a Cool and Dry Place

Protect from Light

Keep out of Reach of Children

6.5 Nature and contents of container

PVC/Aluminium foil blister packs of 10 Tablets. Such 1 blister sachet

In a packet

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

AQUATIX PHARMACEUTICALS LTD
19B, SERIKI ABASS CRESCENT
OFF OSOLO WAY, AJAO ESTATE, ISOLO,
LAGOS STATE, NIGERIA.

MANUFACTURED BY:

GLOBELA PHARMA PVT. LTD
357, GIDC, SACHIN, SURAT,
GUJARAT, INDIA.