SUMMARY OF PRODUCT CHARACTERISTICS OF FEVEREX TABLET

1. NAME OF THE MEDICINAL PRODUCT:

Feverex Tablet.

1.1 Strength

Each tablet contains: Paracetamol 500mg

1.2 Pharmaceutical Form

Oral

2. QUALITATIVE AND QUANTITAVE COMPOSITION

2.1 Qualitative declaration

Paracetamol BP

2.2 Quantitative declaration

Each tablet contains Paracetamol 500mg BP

3. PHARMACEUTICAL FORM

Tablet.

4.0 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Feverex Tablets are recommended for relief of the symptoms of fever associated with colds, flu, malaria as well as other infections.

Feverex Tablets are also recommended for relief of pain due to muscular aches, menstrual discomfort, toothaches, sinutisis, arthritic and rheumatic conditions and other painful and febrile conditions.

4.2 Posology and Method of Administration

For oral administration only

Adults: One or two tablets every three to four hours.
Do not exceed 4 tablets in 24 hours.
Children: 6 – 12 years: ½ to 1 tablet after three hours.
Suspension formulation is recommended for young children.

4.3 Contraindications

Feverex Tablets are contra-indicated in patients with hypersensitivity**.**

4.4 Special Warnings and Precautions for Use

Warning: Do not exceed the stated doses.

Precautions: Should be given with care to patients with impaired kidney or liver function. Although Feverex is very effective in managing fever associated with malaria and other infections, it is not a cure and should be used in combination with suitable anti-infectives

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol

Anticoagulants - the effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding. Occasional doses have no significant effect.

• Metoclopramide – may increase speed of absorption of paracetamol.

• Domperidone – may increase speed of absorption of paracetamol.

• Colestyramine – may reduce absorption if given within one hour of paracetamol.

• Imatinib - restriction or avoidance of concomitant regular paracetamol use should be taken with imatinib.

4.6 Adverse Reactions

Adverse reactions are rare but may include skin rashes and hematological reactions. Vomiting, gastroinstenial edema, liver damage and renal tubular necrosis may occur following over dosage.

4.7 Overdose

Symptoms of paracetamol over dosage include vomiting, gastrointestinal hemorrhage, liver damage, cerebral edema and renal tubular neurosis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacological Properties

ATC Code: **N02BE01**

Paracetamol:

Paracetamol is thought to act primarily in the CNS, increasing the pain threshold by inhibiting both isoforms of cyclooxygenase, COX-1, COX-2, and COX-3 enzymes involved in prostaglandin (PG) synthesis. Unlike NSAIDs, acetaminophen does not inhibit cyclooxygenase in peripheral tissues and, thus, has no peripheral anti-inflammatory affects. While aspirin acts as an irreversible inhibitor of COX and directly blocks the enzyme's active site, studies have found that paracetamol indirectly blocks COX, and that this blockade is ineffective in the presence of peroxides. This might explain why paracetamol is effective in the central nervous system and in endothelial cells but not in platelets and immune cells which have high levels of peroxides. Studies also report data suggesting that paracetamol selectively blocks a variant of the COX enzyme that is different from the known variants COX-1 and COX-2. This enzyme is now referred to as COX-3. Its exact mechanism of action is still poorly understood, but future research may provide further insight into how it works. The antipyretic properties of paracetamol are likely due to direct effects on the heat-regulating centres of the hypothalamus resulting in peripheral vasodilation, sweating and hence heat dissipation.

5.2 Pharmacokinetic Properties

Paracetamol

Paracetamol has analgesic and antipyretic properties but it has no useful anti-inflammatory properties.

Paracetamol's effects are thought to be related to inhibition of prostaglandin synthesis.

Paracetamol, unlike other common analgesics such as aspirin and ibuprofen, has no anti-inflammatory properties or effects on platelet function, and it is not a member of the class of drugs known as non-steroidal anti-inflammatory drugs or NSAIDs. At therapeutic doses acetaminophen does not irritate the lining of the stomach nor affect blood coagulation, kidney function, or the fetal ductus arteriosus (as NSAIDs can). Like NSAIDs and unlike opioid analgesics, acetaminophen does not cause euphoria or alter mood in any way.

5.3 Preclinical safety data

There is no preclinical safety data of paracetamol and any other ingredients used in the manufacture of Feverex Tablets.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone, Lactose, Maize Starch, Potassium Sorbate, Magnesium Stearate and Purified Water.

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool dry place below 30^0C. Keep out of reach of children

6.5 Nature and contents of container

FEVEREX TABLETS are packed in ALU-PVC blister packs of two contained in a unit box with literature insert.

6.6 Special precautions for disposal and other handling

No special requirements

7.0 Name & Address of Manufacturer

Name: BETA HEALTHCARE INTERNATIONAL LTD
Address: Plot No. LR 209/6554, Mogadishu Road, Industrial Area
P.O. BOX 42569-00100 GPO Nairobi
Country: KENYA
Telephone: +25420530106/8
Telefax: +25420556198 / 2944
E-Mail: info@ke.betashelys.com

8. Marketing Authorization Number

9. Date of First Registration/Renewal of the Registration

10. Date of revision of the text

February 2019

11. Dosimetry

Not Applicable

12. Instructions for Preparation of Radiopharmaceuticals

Not Applicable