

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Product Name: Ibumed Suspension

Generic Name: Ibuprofen 10mg

Page No: 1 of 6

1.0. Name of the Medicinal Product:

IBUMED Oral Suspension.

2.0. Qualitative and quantitative composition:

Each 5ml oral suspension contains Ibuprofen 100mg.

3.0. Pharmaceutical form:

Liquid Suspension.

4.0. Clinical particulars:

4.1 Therapeutic indication:

IBUMED for children gives relief by changing the body's response to high temperature, pain and swelling. It contains the active ingredient Ibuprofen, which belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs); it acts by targeting the source of fever and pain.

4.2 Posology and method of administration:

The medicine is for short term use only. If your child's symptoms persist for more than 3 days consult your doctor.

Babies 6 – 12 months: Give 2.5ml three to four times in 24 hours.

Children 1 – 3 years: Give 5ml three times in 24 hours.

Children 4 – 6 years: Give 7.5ml (5ml + 2.5ml) three times in 24 hours.

Children 10 – 12 years: Give 15ml three times in 24 hours.

WARNING: Do not exceed the stated dose.

FEVER INDUCED BY IMMUNIZATION

Only give this product to a baby under 6 months old if your doctor tells you to.

-Give 2.5ml, if necessary give a further 2.5ml 6 hours later.

-Do not give more than 5ml in 24 hours

If the fever is not reduced, do not give a third dose, but consult your doctor.

4.3 Contraindications:

Do not give babies or children

-Who are allergic to aspirin

-Who have had stomach ulcers or other stomach disorders

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Product Name: Ibumed Suspension

Generic Name: Ibuprofen 10mg

Page No: 2 of 6

- Who suffer a worsening of asthma, runny nose or hives due to aspirin or other similar medicines
- Who are sensitive to any of the active ingredients

4.4 Special warnings and precautions for use

Please talk to your doctor (or pharmacist) before giving IBUMED for children to your child if he/she

- suffers from asthma
- has liver, kidney or heart problems
- is taking any other medicines or treatment which involves pain relieve or other NSAIDs such as ibuprofen or aspirin, blood thinning drugs (anticoagulants), drugs for high blood pressure (anti-hypertention), diuretics to increase urine output and lithium or methotrexate.

There is a risk of renal impairment in dehydrated children and adolescents

4.5 Interaction with other medicinal products and other forms of interaction:

You or your child are taking other medicines, especially:

- other medicines containing ibuprofen, aspirin or other NSAIDs, including those you can buy over the counter
- diuretics (to help you pass water)
- anticoagulants (blood thinning medicines e.g. warfarin)
- medicines for high blood pressure (e.g. captopril, atenolol, losartan)
- lithium (for mood disorders)
- methotrexate (for psoriasis, arthritis and types of cancer)
- zidovudine (for HIV)
- corticosteroids (an anti-inflammatory drug)
- probenecid (to treat gout)
- aminoglycosides (a type of antibiotic)
- oral hypoglycemic agents (oral medicines to treat diabetes)
- cardiac glycosides (for heart problems)
- ciclosporin or tacrolimus (to prevent organ rejection after transplant)
- quinolone antibiotics (for infections)
- antidepressant drugs
- antiplatelet drugs e.g. dipyridamole, clopidogrel.

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting, e.g. aspirin/acetylsalicylic acid, warfarin, ticlopedine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol or angiotensin II receptor antagonists such as losartan) and other medicines may affect or be affected by treatment

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Product Name: Ibumed Suspension

Generic Name: Ibuprofen 10mg

Page No: 3 of 6

with ibuprofen. You should therefore always seek the advice of a healthcare professional before you use ibuprofen with other medicines.

See the advice of your doctor or pharmacist if any of the above apply. If you are not sure what types of medicines your child is taking, show the medicine to the doctor or pharmacist.

4.6 Fertility, pregnancy and lactation:

The medicine can be used by adults if necessary, however;

-Pregnant women should obtain medical advice before taking this drug.

4.7 Effects on ability to drive and use machines:

There are no known effects on driving or use of machines.

4.8 Side effects:

Although side effects are uncommon, your child may get one of the known side effects of NSAIDs. If they do or you have any concern stop giving the medicine to your child and talk to your doctor as soon possible.

4.9 Overdose:

Problems in overdose are rare, but if you accidentally give more than the recommended dose contact your doctor straight away.

5.0. Pharmacological properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group:

Ibuprofen is a non-steroidal anti-inflammatory drug that has analgesic and antipyretic properties.

Mechanism of action

It is a cyclo-oxygenase inhibitor. It catalyze the conversion of arachidonic acid into prostaglandins; their inhibition is the mode of action of ibuprofen.

5.2 Pharmacokinetic properties:

Absorption

Orally administered

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

6.0. Pharmaceutical particulars:

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Product Name: Ibumed Suspension

Generic Name: Ibuprofen 10mg

Page No: 4 of 6

6.1 List of excipients

Sorbitol Solution

Glycerin

Avicel Rc 591

Sugar

Saccharine Sodium

Tween 80

Citric Acid

Xanthan Gum

Sodium Benzoate

EDTA

F D & C Red No=40

Mixed Fruit Flavour

Strawberry Flavour

Deionised Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

The oral suspension are filled capped and packed in 100ml amber pet bottles/ pack

Each pack contains a dosage cup.

6.6 Special precautions for disposal and other handling

No special requirements.

7.0.Applicant / Manufacturer:

Sterling Drugs Limited,

6, Femi Asiwaju Close, Ojodu Estate,

Ojodu, Lagos.