

1.3.1 Summary of Product Characteristics

1. Name of the medicinal product

M & B Isopropyl alcohol

2. Qualitative and quantitative composition

Alcohol B.P 99.87%

(Isopropyl alcohol 88.02%, Ethanol 11.87%, n-propanol 0.13%, Water 0.01%)

3. Pharmaceutical form

Liquid external preparation

4. Clinical particulars

4.1 Therapeutic indications

For skin disinfection prior to injection or minor surgery

4.2 Posology and method of administration

Posology

Method of administration

For external administration only. Not to be ingested. To be applied on a clean pad and used to wipe the affected area.

4.3 Contraindications

Hypersensitivity to any of the ingredients listed in the formulation.

4.4 Special warnings and precautions for use

Product is flammable. Keep away from naked fire.

The solution is an irritant to eyes and mucous membranes. It should therefore be kept away from these areas. If the solution comes in contact with the eyes, they should be washed promptly and thoroughly with water

To be used with care in newborn babies, especially those born pre-term.

4.5 Interaction with other medicinal products and other forms of interactions

Alcohol should not be brought into contact with some vaccines and skin test injections (patch tests). If in doubt, consult the vaccine manufacturer's literature.

4.6 Fertility, pregnancy and lactation

There are no studies with this product in pregnant or lactating women. No effects during pregnancy and lactation are anticipated, since systemic exposure to isopropyl alcohol is negligible.

4.7 Undesirable effects

Very rarely allergic or irritation skin reactions have been reported with isopropyl alcohol. Usually appearing within the area of application of the solution and rarely spread. They were non serious in nature and include rash, application site erythema, pruritus, pain and were resolved with antihistamines.

4.8 Effects on ability to drive and use machines

None.

4.9 Overdose

There are no reports of overdose with this product

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other Analgesics and Antipyretics (Anilides)

ATC Code: .D08AX05

Mode of action

Isopropyl alcohol is rapidly bactericidal and fast acting broad spectrum antiseptic but is not considered persistent. Its mechanism of action appears to be denaturation of proteins.

Spectrum of antibacterial activity

Isopropyl alcohol (at 70% v/v) has bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria including mycobacteria, but is inactive against bacterial spores.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted with this product.

5.3 Preclinical safety data

. There are no preclinical data of relevance to the prescriber

6. Pharmaceutical particulars

6.1 List of excipients

Purified water

6.2 Incompatibilities

None stated

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C. Protect from light. Keep out of the reach of children.

6.5 Nature and contents of container

Bottles: Amber (Type III) Pet bottle
Closure: HDPE,
Pack sizes: 200ml

Dosing device: None

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local NRA requirements.

7. Marketing authorisation holder

May & Baker Nigeria Plc

1, May & Baker Avenue Off Idiroko Road Ota Ogun State

8. Marketing authorisation number(s)

Not applicable

9. Date of revision of the text

Septemeber 2024