SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GLOMOL is an oral Syrup

Composition:

Each 5ml contains:

Paracetamol BP…….120mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Excipients: Each 5ml also contains Sugar

For a full list of excipients, see section 6.1

3. Pharmaceutical Form

Oral Liquid

Pink coloured Raspberry flavored syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications:

It is indicated for relieving pain, headache, symptoms of cold, influenza, reduction of temperature and relief of joint muscle pains.

4.2 Posology and method of administration:

Posology

Children 7-12 years: Take 20ml up to three to four times a day as required
Children above 1 – 6 years: Take 5ml up to three to four times a day as required
Infants 3months -1 year: Take 2.5ml up to three to four times a day as required

Method of Administration

For oral administration.

4.3 Contraindications

Do not take Glomol Syrup if you are hypersensitive to Paracetamol or any of the other ingredients of GLOMOL Syrup.

4.4 Special warnings and precautions for use

Care is advised in the administration of Paracetamol to patients with severe renal or severe hepatic impairment. Do not exceed the recommended dose.
Do not take Paracetamol for more than 3 days without consulting a doctor.
Do not take with any other Paracetamol-containing products.
If symptoms persist, consult your doctor.
Keep out of the reach of children.

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

The speed of absorption of Paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. The anticoagulant effect of warfarin and other

coumarins may be enhanced by prolonged regular daily use of Paracetamol with increased risk of bleeding.

4.6 Pregnancy and Lactation
Ask your doctor or pharmacist for advice before taking any other medicine**.**

4.7 Effects on the ability to drive and use machines
Paracetamol has no influence on the ability to drive and use machines.

4.8 Undesirable effects:
Get emergency medical help if you have any of these signs of an allergic reaction to Paracetamol: hives; difficulty breathing; swelling of your face, lips, tongue, or throat. Stop using this medication and call your doctor at once if you have a serious side effect such as:

- low fever with nausea, stomach pain, and loss of appetite;
- dark urine, clay-colored stools; or
- jaundice (yellowing of the skin or eyes)

4.9 Overdose
In case of any overdose, treatment will be symptomatic

5. PHARMACOLOGICAL PARTICULARS

5.1 Pharmacodynamic properties
Pharmacotherapeutic Group**:** Analgesic and Antipyretic

ATC Code: N02BE01

Mechanism of action:
The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.
Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulating centre to produce peripheral vaso-dilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2 Pharmacokinetic properties
Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentration occurring about 10 to 60 minutes after oral administration. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increasing concentration. The elimination half-life of Paracetamol varies from about 1 to 3 hours.
Paracetamol is metabolized predominately in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged Paracetamol. A

minor hydroxylated metabolite (N-acetyl -p- benzoquinoneimin) which is usually produced in very small amounts by mixed function oxidases in the liver and kidney and which is usually detoxified by conjugates with gluthathione may accumulate following Paracetamol overdosage and cause tissue damage. half-life is approximately 3-6 hours.

5.3 Pre-clinical Safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients
Sugar
Sodium Methyl Paraben
Sodium Propyl Paraben
Di Sodium EDTA
Sodium Chloride
Peg400
Sorbitol
Colour: Erythrosine
Citric Acid
Flavour Raspbery

6.2 Incompatibilities
Not applicable.

6.3 Shelf Life
36 months.

6.4 Special Precautions for storage
Store below 30^{o}C, protect from light.
Keep out of reach and sight of children.

6.5 Nature and contents of container
100 ml Amber Glass Bottle in a Mono Carton along with a pack insert.

6.6 Special precautions for disposal and other handling
No special requirements.

7. **SUPPLIER**
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