MODULE -1
ADMINISTRATIVE INFORMATION FOR ZITHROCARE - 200 SUSPENSION

1.5.1 SUMMARY OF PRODUCT CHARECTERISTICS

1. NAME OF MEDICINAL PRODUCT
Zithrocare 200 Suspension

2. QUALITATIVE QUANTITATIVE FORMULA

ITEM	DRUG NAME	SCALE MG PER 5 ML	STD QTY PER ONE LITRE
1.	Azithromycin Anhydrous Use: Azithromycin Dihydrate USP, 60 mesh powder (Contains 5% Excess)	200.000 mg (230.263 mg)*	46.053 g[1]
2.	Methylparaben BP	(10.000 mg)*	2.000 g
3.	Propylparaben BP	(1.000 mg)*	0.200 g
4.	Xanthan Gum USP/NF	(15.000 mg)*	3.000 g
5.	Microcrystalline Cellulose BP (PH 101)	(15.000 mg)*	3.000 g
6.	Sodium Carboxy Methyl Cellulose BP	(15.000 mg)*	3.000 g
7.	Sorbitol Solution (70%), BP (Non crystallizing)	(1500 mg)*	300.000 g
8.	Glycerin BP	(1000 mg)*	200.000 g
9.	Polysorbate 80 BP(Tween 80)	(1.500 mg)*	0.300 g
10.	Oil Orange, (5 Folds).	(15.000 mg)*	3.000 g
11.	Menthol BP, (Crystals)	(1.000 mg)*	0.200 g
12.	Butylated Hydroxyanisole BP (BHA)	(0.0015 mg)*	0.300 mg
13.	Colloidal Anhydrous Silica BP (Aerosil)	(15.000 mg)*	3.000 g
14.	Sucralose USP	(5.000 mg)*	1.000 g
15.	Sodium Chloride BP	(25.900 mg)*	5.180 g
16.	Sodium Citrate BP, Dihydrate	(100 mg)*	20.000 g

MODULE -1
ADMINISTRATIVE INFORMATION FOR ZITHROCARE - 200 SUSPENSION

17.	Glycine BP	(4.88 mg)*	0.976 g
18.	Sodium Hydroxide BP,(Pellets)	(9.8 mg)*	1.960 g
19	Sodium Hydroxide BP, (Pellets)	(q.s)*[2]	Approx. 2.000 g
20	Citric Acid Monohydrate BP	(q.s)*[2]	Approx. 2.000 g
21	Purified Water BP	(q.s) *	Approx. 600 mL

NOTES:

* Quantities not to be disclosed. For company information only. Minor rounding incorporated.

1. Added on 'as is' assay basis.

   Azithromycin is having assay limit of NLT 96% and NMT 103% on anhydrous basis.

   Water Content limit is 4.0% to 5.0%

   Input quantity is based on; considering 96% assay on anhydrous basis and 5% water content. (@ maximum input)

2. Item 19 and 20 to be used for pH adjustment

MODULE -1
ADMINISTRATIVE INFORMATION FOR ZITHROCARE - 200 SUSPENSION

3. PHARMACEUTICAL FORM
Liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Otitis media
• Community Acquired Pneumonia
• Respiratory tract infections like
- Bronchitis
- Pharyngitis
- Tonsillitis
• Skin and soft tissue infections

4.2 Posology and method of administration
As directed by the Physician.
Liquid for oral administration.

4.3 Contraindications
1. Hypersensitivity to Azithromycin or any of the macrolide antibiotics.
2. Co-administration with ergot derivatives

4.4 Special warnings and precautions for use
Azithromycin is not recommended for Neonates.

4.5 Fertility, pregnancy and lactation
Pregnancy

There are no adequate data from the use of Azithromycin in pregnant women. In reproduction toxicity studies in animals azithromycin was shown to pass the placenta, but no teratogenic effects were observed. The safety of azithromycin has not been confirmed with regard to the use of the active substance during pregnancy. Therefore Azithromycin should only be used during pregnancy if the benefit outweighs the risk.

Breastfeeding

Azithromycin has been reported to be secreted into human breast milk, but there are no adequate and well-controlled clinical studies in breastfeeding women that have characterized the pharmacokinetics of azithromycin excretion into human breast milk.

Fertility

In fertility studies conducted in rat, reduced pregnancy rates were noted following administration of azithromycin. The relevance of this finding to humans is unknown.

4.6 Effects on ability to drive and use machines

None

4.7 Overdose

Do not exceed the recommended doses. In case of overdosage consult the Physician immediately.

MODULE -1
ADMINISTRATIVE INFORMATION FOR ZITHROCARE - 200 SUSPENSION

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for constipation. Osmotically acting laxatives.

ATC code: A06A D11

Lactulose is a synthetic disaccharide formed from D-galactose and fructose. Lactulose as a prebiotic substance strengthens the growth of bifidobacteria and lactobacilli, whereas Clostridium and Escherichia coli may be suppressed.

In the colon lactulose is metabolised by bacterial enzymes to short chain fatty acids mainly lactic and acetic acid as well as methane and hydrogen. This effect leads to a decrease of the pH-value and an increase of the osmotic pressure in the colon. This causes stimulation of peristalsis and an increase of the water content of the faeces.

5.2 Pharmacokinetic properties

Absorption

The biological availability of azithromycin after oral administration is approximately 37%. Peak plasma levels are achieved 2-3 hours after taking the medicinal product.

Distribution

After oral administration, azithromycin is distributed throughout the entire body. Pharmacokinetic studies have shown clearly higher azithromycin levels in the tissues than in the plasma (up to 50 times the maximum observed concentration in plasma). This indicates that the substance is bound in the tissues in considerable quantities.

Concentrations in the infected tissues, such as lungs, tonsil and prostate are higher than the MRC90 of the most frequently occurring pathogens after a single dose of 500 mg.

The protein binding of azithromycin in serum is variable and varies, depending on the serum concentration, from 52% at 0.05 mg/l to 12% at 0.5 mg/l. The steady state distribution volume is 31.1 l/kg.

Elimination

The terminal plasma-elimination half-life closely follows the tissue depletion half-life from 2 to 4 days.

MODULE -1
ADMINISTRATIVE INFORMATION FOR ZITHROCARE - 200 SUSPENSION

Approximately 12% of an intravenously administered dose of azithromycin is, over a period of 3 days, excreted unchanged in the urine. High concentrations of unchanged azithromycin were found in human bile. In this, ten metabolites were also detected (formed by N- and O-desmethylation, by hydroxylation of the desosamin and aglycon rings and by splitting the cladinose conjugate). A comparison of fluid chromatography and microbiological assessment methods shows that the metabolites are microbiologically inactive.

In animal models high concentrations of azithromycin were found in phagocytes. Also it has been shown that during active phagocytosis higher concentrations of azithromycin are released than during inactive phagocytosis. In animal models this process was shown to contribute to the accumulation of azithromycin in infectious tissue.

6. Pharmaceutical particulars

6.1 List of excipients

Methylparaben BP

Propylparaben BP

Xanthan Gum USP/NF

Microcrystalline Cellulose BP (PH 101)

Sodium Carboxy Methyl Cellulose BP

Sorbitol Solution (70%), BP
(Non crystallizing)

Glycerin BP

Polysorbate 80 BP(Tween 80)

Oil Orange, (5 Folds).

Menthol BP, (Crystals)

Butylated Hydroxyanisole BP (BHA)

Colloidal Anhydrous Silica BP (Aerosil)

Sucralose USP

Sodium Chloride BP

Sodium Citrate BP, Dihydrate

Glycine BP

Sodium Hydroxide BP,(Pellets)

Sodium Hydroxide BP, (Pellets)

Citric Acid Monohydrate BP

Purified Water BP

6.2 Incompatibilities
None

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30°C, at a dry place. Protect from light.

Keep medicines out of reach of children

7. Marketing Authorization Holder and

Manufacturer

MEYER ORGANICS PVT. LTD

10 D, II nd Phase, Peenya Industrial Area,

Bangalore, 560 058, India