1. Name of the medicinal Product

Albendazole Suspension $200 \mathrm{mg} / 5 \mathrm{ml}$ (ANTHEL)

### 1.1 Strength

Each 5 ml of the suspension contains 200 mg of Albendazole USP.

### 1.2 Pharmaceutical Form <br> Oral Suspension

## 2. Qualitative and Quantitative Composition

### 2.1 Qualitative declaration

Albendazole USP

### 2.2 Quantitative declaration

Each 5 ml of the suspension contains 200 mg of Albendazole USP.
For full list of Excipients, see section 6.1.

## 3. Pharmaceutical Form

Oral Suspension
Pink colour suspension having pleasant odour and sweet taste, filled in amber colour pet bottle.
Distribution Category: Prescription Only Medicines (POM)

## 4. Clinical Particulars

### 4.1 Therapeutic Indications

Albendazole indicated for the treatment of following infections:
Neurocysticercosis: Albendazole is indicated for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, Taenia solium.

Hydatid Disease: Albendazole is indicated for the treatment of cystic hydatid disease of the liver, lung and peritoneum, caused by the larval form of the dog tapeworm, Echinococcus granulosus.

### 4.2 Posology

Adults and children over two years: 10 ml suspension ( 400 mg ) as a single dose.

Children (1-2 y ears): 5 ml suspension ( 200 mg ) as a single dose.
Neurocysricercosis \& Hydatid Disease:
$<60 \mathrm{~kg}: 15 \mathrm{mg} / \mathrm{kg} /$ day in 2 divided doses (maximum: $800 \mathrm{mg} /$ day ), administered 400 mg ( 10 ml ) twice daily with meals for 28 days, followed by a 14-day albendazole-free interval. Repeat for a total of 3 dosage cycles.
$\geq 60 \mathrm{~kg}: 400 \mathrm{mg}(10 \mathrm{ml})$ twice daily with meals for 28 days, followed by a 14-day albendazole free interval. Repeat for a total of 3 dosage cycles.

### 4.3 Method of Administration

Oral Suspension

### 4.4 Contraindications

Albendazole should not be administered during pregnancy or in women thought to be pregnant. Contraindicated in persons known to be hypersensitive to albendazole or any component.

### 4.5 Special Warnings and Special Precautions for Use

Neurocysticercosis: For appropriate use of albendazole, corticosteroids should be administered before or upon initiation of albendazole therapy to minimize inflammatory reactions and prevent cerebral hypertension. Anticonvulsant therapy should be used concurrently during the first week of therapy to prevent seizures.
Albendazole has been noted that leucopenia has occurred when used for periods longer than recommended.

Albendazole should be discontinued in all patients if clinically significant decreases in blood cell counts occur.
Use with caution in patients with hepatic or renal disease.

### 4.6 Pediatric Population

Children (1-2 y ears): 5 ml suspension ( 200 mg ) as a single dose.
Neurocysricercosis \& Hydatid Disease:
$<60 \mathrm{~kg}: 15 \mathrm{mg} / \mathrm{kg} /$ day in 2 divided doses (maximum: $800 \mathrm{mg} /$ day ), administered 400 mg ( 10 ml ) twice daily with meals for 28 days, followed by a 14-day albendazole-free interval. Repeat for a total of 3 dosage cycles.

### 4.7 Interaction with other medicinal products and other forms of interaction

Cimetidine, praziquantel and dexamethasone have been reported to increase plasma levels of albendazole active metabolite. Ritonavir, phenytoin, carbamazepine and phenobarbital may have potential to reduce plasma concentrations of albendazole sulfoxide. Clinical relevance of this is unknown, but may result in decreased efficacy, especially in treatment of systemic helminth infections. Patients should be monitored for efficacy and may require alternative dose regimens or therapies.

### 4.8 Additional information on special populations

No specific Information

### 4.9 Paediatric Population

No specific Information

### 4.10 Pregnancy and Lactation

### 4.10.1 Pregnancy

There are no adequate and well-controlled studies of albendazole administration in pregnant women. Albendazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus and only when no alternative management is appropriate.

### 4.10.2 Lactation

It is excreted in human milk. Caution should be exercised when albendazole is administered to a nursing woman.

### 4.11 Effects on ability to Drive and use Machines

Adverse effects with albendazole suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$ oral suspension on the ability to drive or operate machinery have not been observed.

### 4.12 Undesirable Effects

Common adverse effects: Epigastric pains, diarrhoea, headache, nausea, vomiting, dizziness, constipation, purities and dry mouth.

### 4.13 Overdose

Symptomatic therapy (e.g., gastric lavage and activated charcoal) and general supportive measures are recommended.

## 5. Pharmacological Properties

### 5.1 Pharmacodynamics Properties

Albendazole is a broad-spectrum anthelmintic, which is highly effective against a wide range of intestinal helminths. Albendazole is also effective against tissue helminth infections, such as cutaneous larva migrans (see Therapeutic Indications). Albendazole therapy has also been used in the high dose, long term treatment of tissue helminths infections including hydatid cysts and cysticercosis. The antihelminthic action of albendazole is thought to be mainly intra-intestinal. However, at higher albendazole doses, sufficient is absorbed and metabolised to the active sulphoxide metabolite, to have a therapeutic effect against tissue parasites. Albendazole exhibits larvicidal, ovicidal and vermicidal activity, and is thought to act via inhibition of tubulin polymerization. This causes a cascade of metabolic disruption, including energy depletion, which immobilizes and then kills the susceptible helminth.

### 5.2 Pharmacokinetic Properties

Absorption: Poorly absorbed from GI tract because of low aqueous solubility. Rapidly converted to active metabolite (albendazole sulfoxide) before reaching systemic circulation. Peak plasma concentrations of albendazole sulfoxide attained 2-5 hours after dosing.
Distribution: It is 70\% bound to plasma protein and is widely distributed throughout the body; it has been detected in urine, bile, liver, cyst wall, cyst fluid, and cerebral spinal fluid (CSF).
Metabolism and Elimination: Albendazole is rapidly converted in the liver to the primary metabolite, albendazole sulfoxide, which is further metabolized to albendazole sulfone and other primary oxidative metabolites that have been identified in human urine. Urinary excretion of albendazole sulfoxide is a minor elimination pathway with less than $1 \%$ of the dose recovered in the urine. Biliary elimination presumably accounts for a portion of the elimination as evidenced by biliary concentrations of albendazole sulfoxide similar to those achieved in plasma.

### 5.3 Preclinical Safety Data

Not Applicable

## 6. Pharmaceutical Particulars

### 6.1 List of Excipients

Sodium methyl hydroxybenzoate
Sodium propyl hydroxybenzoate
Disodium Edetate
Carmellose sodium HVP
Sucrose
Citric acid Monohydrate
Sodium citrate
Aspartame
Polysorbate 80 (Tween 80)
Ess. Mixed fruit
Purified Water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf Life

36 months

### 6.4 Special Precautions for Storage

Do not store above $30^{\circ} \mathrm{C}$. Protect from light.

### 6.5 Nature and Contents of Container

10 ml amber PET bottle having 25 mm aluminum cap with LPL logo and 10 ml plastic measuring cup. Such 1 bottle is packed in a printed carton with packing insert.

### 6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.
7. Marketing Authorization Holder and Manufacturing Site Addresses

### 7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal.-Kalol,
Dist.- Gandhinagar, Gujarat State, India.
Telephone no.: +91-079-41078096
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

### 7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal.-Kalol,
Dist.- Gandhinagar, Gujarat State, India.
Telephone no.: +91-079-41078096
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com
8. Marketing Authorization Number

Rwanda FDA-HMP-MA-0807
9. Date of First < Registration $>/$ Renewal of The $<$ Registration $>$
15.01.2024
10. Date of Revision of the Text

January, 2024

## 11. Dosimetry (If Applicable)

Not Applicable
12. Instructions for preparation of radiopharmaceuticals

Not Applicable

# Annexure II Patient Information Leaflet (PIL). 

 (Enclosed)
## PATIENT INFORMATION LEAFLET ALBENDAZOLE SUSPENSION 200 MG/5ML [ANTHEL]

## (Albendazole USP)

## Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.
If you have any further questions, ask your physician, health care provider or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

## WHAT IS IN THIS LEAFLET:

1. What Albendazole Suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$ is and what it is used for
2. Before you use Albendazole Suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$
3. How to use Albendazole Suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$
4. Possible side effects
5. How to store Albendazole Suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$
6. Further information

## 1. WHAT ALBENDAZOLE SUSPENSION $200 \mathrm{MG} / 5 \mathrm{ML}$ IS AND WHAT IT IS USED FOR

It contain active ingredient albendazole. It is a benzimidazole anthelmintic used to treat parenchymal neurocysticercosis and other helminth infections. It is indicated in for single or mixed intestinal infections caused by Enterobius vermicularis (Pinworm, Threadworm), Trichuris trichiura (Whipworm), Ascaris lumbricoides (Roundworm), Ancylostoma duodenale \& Necator americanus (Hookworm), Taenia Saginata (Tapeworm), infections, when other susceptible helminths species are present. Treatment courses should be extended to 3 days. Strongyloides stercoralis. Also, in giardiasis in children over 2 years of age. Treatment of parenchymal neurocysticercosis caused by cystic hydatid disease of liver, lung \& peritoneum caused by Echinococcus granulosus.

## 2. BEFORE YOU USE ALBENDAZOLE SUSPENSION $200 \mathrm{MG} / 5 \mathrm{ML}$

Do not use albendazole suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$. If you are allergic (known hypersensitivity) to albendazole or any of the other ingredients or any other medicines. It should not be administered during pregnancy or in women thought to be pregnant.
Take special care with albendazole suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$ oral suspension: Warnings and Precautions: Talk to your Physician or pharmacist before taking albendazole suspension 200 $\mathrm{mg} / 5 \mathrm{~mL}$ oral suspension. Neurocysticercosis: For appropriate use of albendazole, corticosteroids should be administered before or upon initiation of albendazole therapy to minimize inflammatory reactions and prevent cerebral hypertension. Anticonvulsant therapy should be used concurrently during the first week of therapy to prevent seizures. It has been noted that leucopenia has occurred when used for periods longer than recommended. It should be discontinued in all patients if clinically significant decreases in blood cell counts occur. Use with caution in patients with hepatic or renal disease. Use of albendazole in patients with impaired renal or hepatic function has not been studied. However, use with caution in patients with pre-existing liver disease, since albendazole is metabolized by liver and has been associated with idiosyncratic hepatotoxicity. Use in Children: It is not recommended in children under 2 years of age due to limited experience. Talk to your Physician or pharmacist if the fungal infection does not improve, as alternative antifungal therapy may be needed.
Taking other medicines: Please tell your Physician, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Cimetidine, praziquantel and dexamethasone have been reported to increase plasma
levels of albendazole active metabolite. Ritonavir, phenytoin, carbamazepine and phenobarbital may have potential to reduce plasma concentrations of albendazole sulfoxide. Clinical relevance of this is unknown, but may result in decreased efficacy, especially in treatment of systemic helminth infections. Patients should be monitored for efficacy and may require alternative dose regimens or therapies. Taking albendazole suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$ oral suspension with food and drink: Patients can take your medicine with or without a meal or as directed by physician. Pregnancy and breast-feeding: Ask your physician, health care provider or pharmacist for advice before taking any medicine. Pregnancy: Pregnancy Category C: It should not be used during pregnancy. Lactation: It is excreted in human milk. Caution should be exercised when albendazole is administered to a nursing woman. Caution for use: It contain. Sucrose: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucraseisomaltase insufficiency should not take this medicine. Liquid Sorbitol: Patients with hereditary fructose intolerance (HFI) should not take/be given. Sodium Benzoate: It may increase jaundice (yellowing of the skin and eyes) in new-born babies (up to 4 weeks old). Sodium Methyl Hydroxybenzoate, Sodium Propyl Hydroxybenzoate: May cause allergic reactions (possibly delayed). Driving and using machines: Adverse effects with albendazole suspension $200 \mathrm{mg} / 5$ mL oral suspension on the ability to drive or operate machinery have not been observed.

## 3. HOW TO USE ALBENDAZOLE SUSPENSION 200 MG/5 ML:

Method of administration: It should be administered orally. Shake well before use. Patient should swallow albendazole suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$ oral suspension. It is best to take your oral suspension at the same time each day. Always use albendazole suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$ oral suspension exactly as your Physician has told you. It should be taken with or without meals or as directed by physician. The dosage schedule of albendazole suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$ oral suspension is mentioned follow: Adults and children over two years: 10 ml suspension ( 400 mg ) as a single dose. Children ( $1-2$ years): 5 ml suspension ( 200 mg ) as a single dose. Neurocysticercosis: Body weight $<60 \mathrm{~kg}$ : $15 \mathrm{mg} / \mathrm{kg} /$ day in 2 divided doses (maximum: 800 $\mathrm{mg} /$ day $)$, administered $400 \mathrm{mg}(10 \mathrm{ml})$ twice daily with meals for $8-30$ days. Body weight $\geq 60 \mathrm{~kg}$ : $400 \mathrm{mg}(10 \mathrm{ml})$ twice daily with meals for $8-30$ days. Hydatid Disease: Body weight $<60 \mathrm{~kg}$ : 15 $\mathrm{mg} / \mathrm{kg} / \mathrm{day}$ in 2 divided doses (maximum: $800 \mathrm{mg} /$ day), administered $400 \mathrm{mg}(10 \mathrm{ml})$ twice daily with meals for 28 days, followed by a 14 -day albendazole-free interval. Repeat for a total of 3 dosage cycles. Body weight $\geq 60 \mathrm{~kg}: 400 \mathrm{mg}(10 \mathrm{ml})$ twice daily with meals for 28 days, followed by a 14-day albendazole -free interval. Repeat for a total of 3 dosage cycles. Giardiasis: A single dose of $400 \mathrm{mg}(10 \mathrm{ml})$ for five days.
If you take more albendazole suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$ oral suspension than you should: If you accidentally take too many albendazole suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$ oral suspension, tell your physician at once or contact your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken. The Symptomatic therapy (e.g., gastric lavage and activated charcoal) and general supportive measures are recommended.
If you forget to take albendazole suspension $200 \mathbf{m g} / \mathbf{5} \mathbf{~ m L}$ oral suspension: Do not take a double dose to make up for a forgotten dose. If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. If any further questions on the use this contact your Physician or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, albendazole suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$ oral suspension can cause side effects, although not everybody gets them. Check with your Physician immediately if any of the following side effects occur: Abdominal pain. Diarrhoea, nausea, vomiting, dizziness, itchiness and/or skin
rashes, bone pain, proteinuria, and low red cell count. Leucopenia and transiently raised hepatic enzymes Hypersensitvity reactions including rash, pruritis and urticaria. During prolonged higher dose albendazole therapy of hydatid disease, reports of severe hepatic abnormalities, including jaundice and hepatocellular damage which may be irreversible if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

## 5. HOW TO STORE ALBENDAZOLE SUSPENSION 200 MG/5 ML

Keep this medicine out of the sight and reach of children. Do not store above $30^{\circ} \mathrm{C}$. Protect from light. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

## 6. FURTHER INFORMATION

It contains: The active substance is albendazole USP. The other ingredient(s) is (are): Xanthan gum BP, Sucrose BP, Liquid sorbitol (Non-Crystallising) BP, Methyl hydroxybenzoate (Methylparaben) BP, Propyl hydroxybenzoate (Propylparaben) BP, Anhydrous citric acid BP, Sodium benzoate BP, Carmellose sodium HVP (Carboxy methylcellulose sodium) BP, Polysorbat-80 (Tween-80) BP, Sodium citrate BP, Ess. Anise, Erythrosine (Supra) Purified water BP. SHELF LIFE: 36 months. Pack: Albendazole Suspension $200 \mathrm{mg} / 5 \mathrm{~mL}$ Oral Suspension: 10 ml amber PET bottle having 25 mm aluminum cap with LPL logo and 10 ml plastic measuring cup. Such 1 bottle is packed in a printed carton with packing insert.

## Manufactured by:

## Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Tal.:- Kalol,
Dist.:- Gandhinagar, Gujarat State, India.
Telephone No: +91-079-41078096
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com
For any information about this medicinal product, please contact the local representative of the supplier:

| Lincoln Pharmaceuticals Limited |
| :--- |
| Trimul Estate, Khatraj, Tal.:- Kalol, |
| Dist.:- Gandhinagar, Gujarat State, India. |
| Telephone No: +91-079-41078096 |
| Email: |
| hiren@lincolnpharma.com |
| Website: $\underline{\text { www.lincolnpharma.com }}$ |

Abacus Pharma (A) Ltd<br>Kigali city market, B1-R85,<br>PO Box 4344, Kigali, Rwanda.<br>Telephone No: +91-079-41078096<br>Email: abacuspharmacist $@$ gmail.com

## Date of publication or revision

27.01.2024

## Annexure III <br> Revised Artwork and Package Insert. (Enclosed)

| Each 5 ml contains: | Albendazole | Mfg. Lic. No. : G/25/1419 |  |
| :---: | :---: | :---: | :---: |
| Albendazole USP $\quad 200 \mathrm{mg}$ | Suspension | Reg. No. : |  |
| Flavoured Syrupy Base Q .S. Approved colour used | $200 \mathrm{mg} / 5 \mathrm{ml}$ |  |  |
| Approved colour used Preservative: |  | Batch No. : |  |
| Methyl Paraben BP 6.6 mg | AN E E | Mfg. Date : |  |
| Propyl Paraben BP $\quad 1.1 \mathrm{mg}$ | For Paediatric Use | Exp. Date : |  |
| Dosage : <br> As directed by the Physician. |  |  |  |
| WARNING : THIS PRODUCT CONTAINS SUCROSE. | 10 L | Manufactured by : <br> LINCOLN PHARMACEUTICALS LTD. <br> Trimul Estate, Khatraj, Tal.-Kalol, Dist.- Gandhinagar, Gujarat State, India. | N |
| SHAKE WELL BEFORE USE. |  |  | \% |



COMPOSITION :
Each 5 ml contains:
Albendazole USP 200 mg
Flavoured Syrupy Base Q.S.
Approved colour used
Preservative:
Methyl Paraben BP $\quad 6.6 \mathrm{mg}$
Propyl Paraben BP $\quad 1.1 \mathrm{mg}$

## THERAPEUTIC CLASS :

Anthelmintic

## PHARMACOLOGICAL ACTION :

Albendazole causes degenerative alterations in the intestinal cells of the worm by inhibiting polymerisation or assembly of tubules into microtubules. The loss of the cytoplasmic microtubules leads to impaired uptake of glucose by the larval and adult stages of the susceptible parasites and depletes their glycogen stores. Degenerative changes in the endoplasmic reticulum, the mitochondria of the germinal layer and subsequent release of lysosomes result in decreased production of ATP, which is the energy required for the survival of the helminth. Due to diminished energy production, the parasite is immobilized and eventually dies.
Pharmacokinetic : Absorption : Poorly absorbed from GI tract because of low aqueous solubility. Rapidly converted to active metabolite (albendazole sulfoxide) before reaching systemic circulation. Peak plasma concentrations of albendazole sulfoxide attained 2-5 hours after dosing.
Distribution : It is $70 \%$ bound to plasma protein and is widely distributed throughout the body; it has been detected in urine, bile, liver, cyst wall, cyst fluid, and cerebral spinal fluid (CSF).
Metabolism and Elimination : Albendazole is rapidly converted in the liver to the primary metabolite, albendazole sulfoxide, which is further metabolized to albendazole sulfone and other primary oxidative metabolites that have been identified in human urine. Urinary excretion of albendazole sulfoxide is a minor elimination pathway with less than $1 \%$ of the dose recovered in the urine. Biliary elimination presumably accounts for a portion of the elimination as evidenced by biliary concentrations of albendazole sulfoxide similar to those achieved in plasma.
HalfLife : Plasma half life of albendazole is 8-12 hours.

## INDICATIONS :

Albendazole indicated for the treatment of following infections:
Neurocysticercosis : Albendazole is indicated for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, Taenia solium.
Hydatid Disease : Albendazole is indicated for the treatment of cystic hydatid disease of the liver, lung and peritoneum, caused by the larval form of the dog tapeworm, Echinococcus granulosus.

## CONTRAINDICATIONS :

Albendazole is contraindicated in patients with known hypersensitivity to the benzimidazole class of compounds or any components of the formulation.

## SPECIALPRECAUTIONS AND WARNING:

Neurocysticercosis : For appropriate use of albendazole, corticosteroids should be administered before or upon initiation of albendazole therapy to minimize inflammatory reactions and prevent cerebral hypertension. Anticonvulsant therapy should be used concurrently during the first week of therapy to prevent seizures.
Albendazole has been noted that leucopenia has occurred when used for periods longer than recommended. Albendazole should be discontinued in all patients if clinically significant decreases in blood cell counts occur.

Use with caution in patients with hepatic or renal disease.
Pregnancy : Category $C$ : There are no adequate and well-controlled studies of albendazole administration in pregnant women. Albendazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus and only when no alternative management is appropriate.
Lactation : It is excreted in human milk. Caution should be exercised when albendazole is administered to a nursing woman.
Caution for use: It contain. Sucrose: Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. Liquid Sorbitol: Patients with hereditary fructose intolerance (HFI) should not take/be given. Sodium Benzoate: It may increase jaundice (yellowing of the skin and eyes) in new-born babies (up to 4 weeks old). Sodium Methyl Hydroxybenzoate, Sodium Propyl Hydroxybenzoate: May cause allergic reactions (possibly delayed).

## ADVERSE EFFECTS :

Common adverse effects: Epigastric pains, diarrhoea, headache, nausea, vomiting, dizziness, constipation, purities and dry mouth.

## DOSAGEAND DIRECTIONS FOR USE :

Adults and children over two years : 10 ml suspension $(400 \mathrm{mg})$ as a single dose.
Children ( $1-2$ years) : 5 ml suspension $(200 \mathrm{mg}$ ) as a single dose.
Neurocysticercosis:
$<60 \mathrm{~kg}$ : $15 \mathrm{mg} / \mathrm{kg} /$ day in 2 divided doses (maximum: $800 \mathrm{mg} /$ day), administered $400 \mathrm{mg}(10 \mathrm{ml})$ twice daily with meals for 8-30 days.
$\geqslant 60 \mathrm{~kg}: 400 \mathrm{mg}(10 \mathrm{ml})$ twice daily with meals for 8-30 days.
Hydatid Disease:
$<60 \mathrm{~kg}: 15 \mathrm{mg} / \mathrm{kg} /$ day in 2 divided doses (maximum: $800 \mathrm{mg} /$ day), administered $400 \mathrm{mg}(10 \mathrm{ml})$ twice daily with meals for 28 days, followed by a 14-day albendazole-free interval. Repeat for a total of 3 dosage cycles.
$\geqslant 60 \mathrm{~kg}: 400 \mathrm{mg}(10 \mathrm{ml})$ twice daily with meals for 28 days, followed by a 14-day albendazole -free interval.
Repeat for a total of 3 dosage cycles.
Use the suspension within 28 days after opening the container.

## OVERDOSAGE:

Symptomatic therapy (e.g., gastric lavage and activated charcoal) and general supportive measures are recommended.

## DRUG INTERACTIONS :

Cimetidine : Albendazole sulfoxide concentrations in bile and cystic fluid may increase in hydatid cyst patients treated with cimetidine.
Praziquantel : Praziquantel may increase the plasma levels of the albendazole sulfoxide.
Dexamethasone : Steady-state trough concentrations of albendazole sulfoxide may high about $56 \%$ when co-administration of dexamethasone with albendazole neurocysticercosis patients.

## PRESENTATION :

Bottle pack

## STORAGE CONDITION :

Do not store above $30^{\circ} \mathrm{C}$. Protect from light.

## Manufactured by :

Trimul Estate, Khatraj, Tal.-Kalol,
Dist.- Gandhinagar, Gujarat State, India.
E-mail : info@lincolnpharma.com
Website : www.lincolnpharma.com

