National Deworming Day
(Single Dose Albendazole to 1-19 years old children)

ADR Profile of Albendazole and its Management

Prepared By

ADR Monitoring Center
(Under Pharmacovigilance Program of India)
Department of Pharmacology
All India Institute of Medical Sciences
G.E. Road, Tatibandh
Raipur – 492099, Chhattisgarh

Adverse Drug Reactions (Single dose Albendazole)

- Adverse effects are usually mild and resolve without treatment.
- Temporary minor reactions following treatment occur mainly in infected people and usually the body's response to the dying of worms.
- Heavily infected people are more likely to experience adverse reactions.
- The chances of adverse reactions are highest at the first round of treatment and tend to decrease during subsequent rounds.

The following is the list of adverse effects which may occur during single dose Albendazole therapy

Sr. No.	Anticipated Adverse effect	Management
1	Mild abdominal Pain	• Bed rest • Tab. Dicyclomine/Oral Suspension o **1 – 2 years:** 5 mg stat. If required, dose of 5 mg can be repeated every 6-8 hourly (Maximum daily dose 40 mg) o **2 – 12 years:** 10 mg stat. If required, dose of 10 mg can be repeated every 8 hourly o **> 12 years:** 20 mg stat. If required, dose of 20 mg can be repeated every 8 hourly • Refer to nearest healthcare center, if not relieved
2	Nausea/Vomiting	• Tab. Domperidone o **1 – 12 years:** 250 to 500 micrograms/kg stat. If required, dose of 250 to 500 micrograms/kg can be repeated every 4-6 hours (Maximum dose 2.4 mg/kg or 80 mg in 24 hours) o **> 12 years:** 10 mg stat. If required, dose of 10 mg can be repeated every 4-6 hours (Maximum dose 80 mg in 24 hours) • In case of dehydration, ORS o 1 sachet in 1 litre (4-5 glasses) of clean water. o To be taken 40-70 ml/kg in 4 hours or as much as possible.
3	Diarrhoea	• ORS o 1 sachet in 1 litre (4-5 glasses) of clean water. o To be taken 40-60 ml/kg in 4 hours or as much as possible. • Refer to nearest healthcare center, if not controlled or patient is severely dehydrated which can be assessed by manifestations like drowsiness, generalized weakness, reduced blood pressure, dryness of mouth/skin/mucosa, decreased urine output, dark coloured urine, sunken eyes, reduced skin elasticity and may be unconsciousness.
4	Fatigue	• Bed rest

Sr. No.	Anticipated Adverse effect	Management

5	Fever	• Tab. Paracetamol/Oral Suspension
		  ○ **1 – 2 years:** 60 mg stat. If required, dose of 60 mg can be repeated every 4-6 hours (Maximum 4 doses in 24 hours)
		  ○ **2 – 4 years:** 180 mg stat. If required, dose of 180 mg can be repeated every 4-6 hours (Maximum 4 doses in 24 hours)
		  ○ **4 – 8 years:** 240 mg stat. If required, dose of 240 mg can be repeated every 4-6 hours (Maximum 4 doses in 24 hours)
		  ○ **8 – 10 years:** 375 mg stat. If required, dose of 375 mg can be repeated every 4-6 hours (Maximum 4 doses in 24 hours)
		• **> 10 years:** 500 mg stat. If required, dose of 500 mg can be repeated every 4-6 hours (Maximum 4 doses in 24 hours)
		• Bed rest

6	Headache	• **Tab. Paracetamol** ○ Dosage same as above

7	Urticaria	• Tab. Chlorpheniramine
		  ○ **1 – 2 years:** 1 mg stat. If required, second dose of 1 mg, after 12 hours
		  ○ **2 – 6 years:** 1 mg stat. If required, dose of 1 mg can be repeated every 4 – 6 hours.
		  ○ **6 – 12 years:** 2 mg stat. If required, dose of 2 mg can be repeated every 4 – 6 hours.
		  ○ **> 12 years:** 4 mg stat. If required, dose of 4 mg can be repeated every 4 – 6 hours
		OR
		• Tab. Cetirizine
		  ○ **2 – 5 years:** 2.5 mg stat. If required, second dose of 2.5 mg, after 12 hours
		  ○ **> 6 years:** 5 mg stat. If required, second dose of 5 mg, after 12 hours
		• **Anaphylactic Reaction may rarely occur which is characterized by** difficulty in breathing, difficulty in swallowing, sudden collapse or very low blood pressure and requires immediate medical attention .

8	Itching	• Tab. Chlorpheniramine/Tab. Cetirizine ○ Dosage same as above

Rare, but serious adverse effect

- Stevens–Johnson syndrome

Role of healthcare worker, in the event of adverse drug reaction:

- Manage adverse drug reaction (ADR) as per table
- In case, ADR is not manageable or severe, refer patient to the nearest healthcare center
- Report ADR, by any one of the following means:
  - ADR Reporting Form (To be filled by Healthcare Care worker) (Form Attached)
    - **Note:** Reporting of ADR does not have any legal implication and confidentiality of reporter and patient is maintained.

- ADR Reporting Form (can be filled by the patient) (Form Attached)
  - Form may be provided to the patient, so as to report adverse effect, if any
- ADR can be reported directly to the National Coordination Center, IPC, Ghaziabad.
  - Refer to www.ipc.gov.in/PvPI/adr.html

OR

Call to Toll Free No. – 1800-180-3024

- Healthcare Worker as well as patient can contact on this Toll Free Number to report suspected ADR

OR

Contact the nearest ADR monitoring centre. (Information regarding this may be obtained from www.ipc.gov.in/PvPI/adr.html.

- AIIMS, Raipur is one of the three (03) recognized ADR monitoring centres in the state of Chhattisgarh.
- The details of ADR Monitoring Centre, AIIMS Raipur is as follows:

Co-ordinator :	**Dr. S.P. Dhaneria** Professor & Head, Dept. of Pharmacology, AIIMS Raipur (C.G.)
Deputy Co-ordinator	**Dr. Nitin Gaikwad** Additional Professor Dept. of Pharmacology, AIIMS Raipur (C.G.)

- To report any suspected Adverse Drug Reaction at AIIMS, Raipur kindly contact at :
  Address: Room No. 2212, ADR Monitoring Center, Department of Pharmacology, 2nd Floor, Medical College Building, Gate No. 5, AIIMS, Tatibandh, GE Road, Raipur – 492099
  Dr Deeptanshu N Chandu – Patient Safety Pharmacovigilance Associate
  Ph: 8695349418/9489234820
  Email: pharmacology@aiimsraipur.edu.in / deeptanshuu@gmail.com

General Precautionary measures:

- Seriously ill individuals (people unable to engage in the normal activities of daily living without assistance because of their illnesses) should be excluded.
- People who are about to receive drugs should be adequately informed about possible adverse reactions and about what they should do in the event of such a reaction.
- People who have previously suffered one of the rare serious adverse experiences caused by reaction to the drugs (e.g. Stevens–Johnson syndrome) should be excluded from treatment.
- Community health personnel should be available throughout the rounds of treatment.
- Scored tablets should be broken into smaller pieces, or crushed, for administration to young children; older children should be encouraged to chew tablet of albendazole. Forcing very small children to swallow large tablets may cause choking or asphyxiation.
- Pregnancy
  - Albendazole can be given in 2nd and 3rd trimester of pregnancy. It should be avoided in 1st trimester of pregnancy.
  - For identification of women who are pregnant and for definition of the stage of pregnancy, the date of a woman's last menstrual period shall be ascertained.

Dosage of Albendazole:

- **1 – 2 years:** 200 mg (Scored tablet to be broken into half and crushed for administration)
- **>2 – 19 years:** 400 mg (1 tablet)