

1.5 DIDANOSINE (ddl)

FORMULATIONS

Chewable tablets (buffered)	Enteric-coated beadlets in capsules	Liquid	FDC
25 mg	125 mg	10 mg/ml	None
50 mg	200 mg		
100 mg	250 mg		
200 mg	400 mg		

DOSE AND DOSE FREQUENCY

Target dose

- Age less than 3 months: 50 mg/m²/dose twice daily
- Age 3 months to 13 years: 90 – 120 mg/m²/dose twice daily

Maximum dose

- Age 13 years or older, or weight more than 60 kg: 200 mg/dose twice daily or 400 mg once daily

Administration – chewable (buffered) tablets

- At least two tablets of appropriate strength must be used at any one time for adequate buffering (e.g. if the child's dose is 50 mg, administer two 25 mg tablets instead of one 50 mg tablet).
- ddl tablets should be chewed, crushed or dispersed in water or clear juice before they are taken.
- ddl tablets should not be swallowed whole.

Administration – enteric-coated beadlets in capsules (EC)

- EC capsules should be swallowed whole. If there is no other therapeutic option and the child is too small to swallow capsules, they should be opened and taken with a small quantity of food or liquid, not with a meal.
- The beadlets inside the capsule should not be crushed or chewed, and if the capsules are opened, the beadlets should be sprinkled on a soft food that does not require chewing.
- Opened capsules should be taken immediately after mixing.

Administration – liquid

- It is not easy to use and should be avoided if possible.
- Prior to dispensing, the pharmacist must constitute dry powder with purified water to an initial strength of 20 mg/ml and immediately mix the resulting solution with antacid to a final strength of 10 mg/ml.

Storage

- Keep liquid refrigerated (2 – 8°C).
- Liquid remains stable for 30 days (shake well before using).
- Discard any unused liquid after 30 days.

OTHER COMMENTS

General

- ddl is degraded rapidly unless given as an enteric formulation or combined with buffering agents or antacids.
- In children this effect may be less marked and ddl may not have to be administered on an empty stomach.

Pharmacokinetic data

- PK data are available for all ages. However, pharmacokinetic data in infants less than 2 weeks of age are variable.

Major drug interactions

- TDF and ribavirin are not recommended to be taken with ddl.

Ref: http://packageinserts.bms.com/pi/pi_videx_ec.pdf
<http://www.who.int/hiv/pub/paediatric/antiretroviral/en/index.html>

DIDANOSINE**Recommended dosing based on weight-bands for children >3 months using liquid and chewable tablets**

Weight range (kg)		Target dose 3 months to <13 years: 90–120 mg/m ² /dose twice daily		Dose (ml or tablets)	
Bottom	Top	Formulation		a.m.	p.m.
3	3.9	10	mg/ml liquid	NR	NR
4	4.9	10	mg/ml liquid	NR	NR
5	5.9	10	mg/ml liquid	3 ml	3 ml
6	6.9	10	mg/ml liquid	5 ml	5 ml
7	7.9	10	mg/ml liquid	5 ml	5 ml
8	8.9	10	mg/ml liquid	5 ml	5 ml
9	9.9	10	mg/ml liquid	5 ml	5 ml
10	10.9	10	mg/ml liquid	6 ml	6 ml
11	11.9	10	mg/ml liquid	6 ml	6 ml
12	13.9	10	mg/ml liquid	6 ml	6 ml
14	16.9	25	mg tablet	4	3
17	19.9	25	mg tablet	4	3
20	24.9	25	mg tablet	4	4
25	29.9	25	mg tablet	5	5
30	34.9	25	mg tablet	5	5

Recommended dosing based on weight-bands for children >3 months using chewable tablets					
Weight range (kg)		Target dose 3 months to <13 years: 90–120 mg/m ² /dose twice daily		Dose (tablet)	
Bottom	Top	Formulation		a.m.	p.m.
3	3.9	25	mg tablet	NR	NR
4	4.9	25	mg tablet	NR	NR
5	5.9	25	mg tablet	2	2
6	6.9	25	mg tablet	3	2
7	7.9	25	mg tablet	3	2
8	8.9	25	mg tablet	3	2
9	9.9	25	mg tablet	3	2
10	10.9	25	mg tablet	3	3
11	11.9	25	mg tablet	3	3
12	13.9	25	mg tablet	3	3
14	16.9	25	mg tablet	4	3
17	19.9	25	mg tablet	4	3
20	24.9	25	mg tablet	4	4
25	29.9	25	mg tablet	5	5
30	34.9	25	mg tablet	5	5

Note: 25 mg chewable tablets can be substituted with other strengths to the same mg amount but each a.m. and p.m. dose must always be made up of at least two tablets.

NR not recommended

DIDANOSINE

Recommended once-daily dosing based on weight-bands using enteric-coated capsules

Weight range (kg)		Target dose 240–300 mg/m ² /day		Dose (ml or tablets)
Bottom	Top	Formulation		a.m. or p.m.
3	3.9	NR		NR
4	4.9	NR		NR
5	5.9	NR		NR
6	6.9	NR		NR
7	7.9	NR		NR
8	8.9	NR		NR
9	9.9	NR		NR
10	10.9	125	mg EC capsule	1
11	11.9	125	mg EC capsule	1
12	13.9	125	mg EC capsule	1
14	16.9	200	mg EC capsule	1
17	19.9	200	mg EC capsule	1
20	24.9	125	mg EC capsule	2
25	29.9	125	mg EC capsule	2
30	34.9	125	mg EC capsule	2

NR not recommended