

ATTACHMENT D

Loperamide HCl 2 mg Orally Dissolving Strips / Anti-diarrheal

Drug Facts	
Active ingredient (in each strip) Loperamide HCl 2 mg	Purpose Anti-diarrheal
Use controls symptoms of diarrhea, including Travelers' Diarrhea	
Warnings	
Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl	
Do not use if you have bloody or black stool	
Ask a doctor before use if you have	
<ul style="list-style-type: none"> ▪ fever ▪ mucus in the stool ▪ a history of liver disease 	
Ask a doctor or pharmacist before use if you are taking antibiotics	
When using this product	
▪ tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> ▪ symptoms get worse ▪ diarrhea last for more than 2 days ▪ you get abdominal swelling or bulging. These may be signs of a serious condition. 	
If pregnant or breast-feeding, ask a health professional before use.	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> ▪ drink plenty of clear fluids to help prevent dehydration caused by diarrhea ▪ find right dose on chart. If possible, use weight to dose; otherwise, use age. ▪ place one strip on tongue; strip disintegrates with or without water ▪ if required, fold the strip along the middle and cut (or tear) to halve the dose 	
adults and children 12 years and over	2 strips after the first loose stool; 1 strip after each subsequent loose stool; but no more than 4 strips in 24 hours
children 9-11 years (60-95 lbs)	1 strip after the first loose stool; 1/2 strip after each subsequent loose stool; but no more than 3 strips in 24 hours
children 6-8 years (48-59 lbs)	1 strip after the first loose stool; 1/2 strip after each subsequent loose stool; but no more than 2 strips in 24 hours
children under 6 years (up to 47 lbs)	ask a doctor
Other information	
<ul style="list-style-type: none"> ▪ safety sealed: do not use if pouch is open or torn ▪ store between 20° to 25° C (68° to 77°F) ▪ protect from moisture ▪ use strip immediately after opening individual pouch ▪ read the directions and warnings before use 	
Inactive ingredients	
[Information will be included in the ANDA when submitted]	
Questions or Comments?	
[A telephone number will be included when the ANDA is submitted]	