

**FENOFIBRATE- fenofibrate tablet**  
**MONTELUKAST SODIUM - montelukast sodium tablet, chewable**  
**Food and Drug Administration**

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**Warning Letter**

<https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm588722.htm>

**FENOFIBRATE**

fenofibrate tablet

**Product Information**

<b>Product Type</b>		<b>Item Code (Source)</b>	NDC:43353-248
<b>Reporting Period</b>	20171205-		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>FENOFIBRATE</b> (UNII: U202363UOS) (FENOFIBRIC ACID - UNII: BGF9MN2HU1)	FENOFIBRATE	48 mg

**MONTELUKAST SODIUM**

montelukast sodium tablet, chewable

**Product Information**

<b>Product Type</b>		<b>Item Code (Source)</b>	NDC:43353-252
<b>Reporting Period</b>	20171205-		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>MONTELUKAST SODIUM</b> (UNII: U1O3J18SFL) (MONTELUKAST - UNII: MHM278SD3E)	MONTELUKAST	5 mg

**Labeler** - Food and Drug Administration (927645523)