RISEDRONATE SODIUM- risedronate sodium tablet, delayed release
Zydus Lifesciences Limited

RISEDRONATE SODIUM DELAYED-RELEASE TABLETS

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

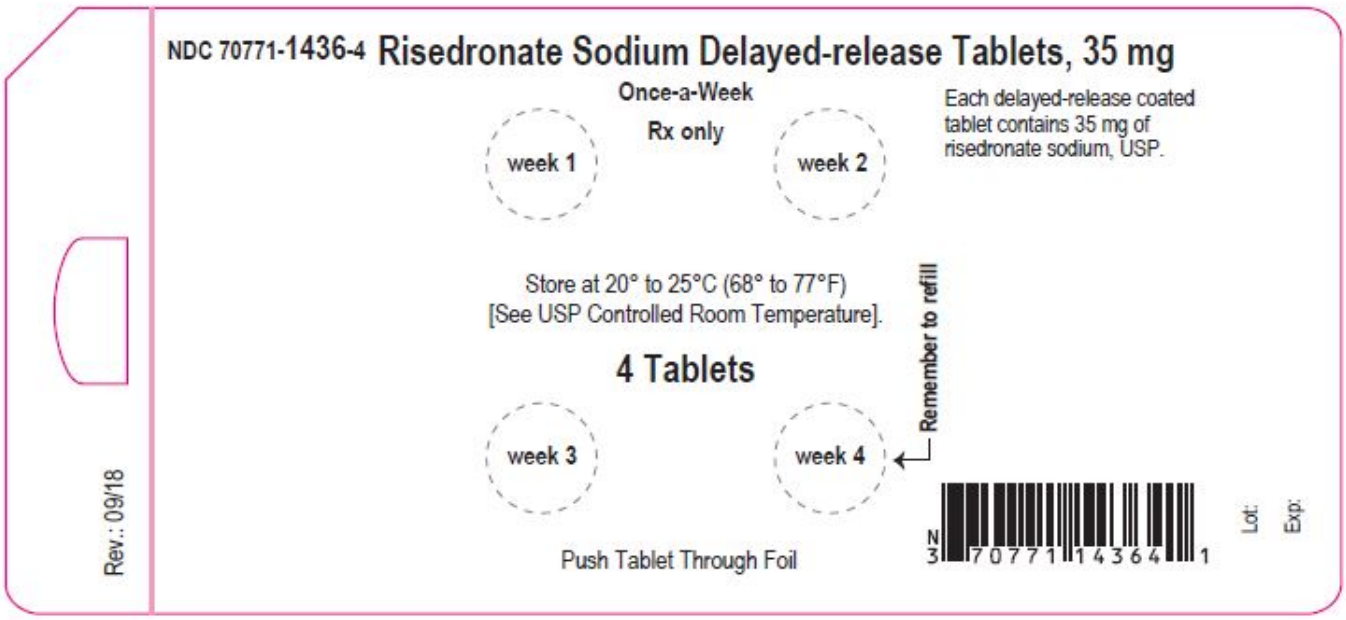
NDC 70771-1436-4 in blister-carton of 4 (1 x 4) Unit-dose Tablets

Risedronate Sodium Delayed-release Tablets, 35 mg

R_X only

4 Tablets

Blister Lidding Foil View



Front View

NDC 70771-1436-4

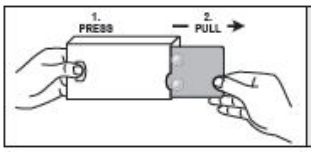
Once-a-Week

Risedronate Sodium Delayed-release Tablets

35 mg

1. PRESS & HOLD HERE

PHARMACIST: Dispense the enclosed Medication Guide to each patient.



OPENING INSTRUCTIONS :
Step 1. Use thumbnail to push the button gently.
Step 2. While holding the button down, pull out the silver medication card.

2. PULL OUT HERE

zydus pharmaceuticals

Rx only

4 (1 x 4) Unit-dose Tablets

Back View

Each delayed-release coated tablet contains 35 mg of risedronate sodium, USP.

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

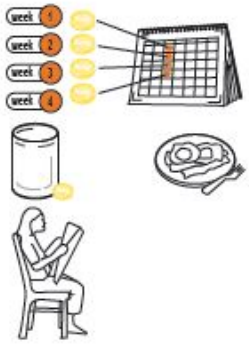
Rev.: 09/18

Follow These Steps for Taking Risedronate Sodium Delayed-release Tablets

Pick a convenient day of the week to take your Risedronate Sodium Delayed-release Tablets, 35 mg

Your Risedronate Sodium Delayed-release Tablet should be taken on the **same day** every week.
Please read the enclosed Medication Guide for full patient information.

1. Take Risedronate Sodium Delayed-release Tablet in the morning immediately following breakfast with at least 4 ounces of plain water. Swallow the tablet whole.
2. **Do not** lie down for at least 30 minutes. **Do not** chew, cut, or crush the tablet. Take calcium supplements, antacids, magnesium-based supplements or laxatives and iron preparations at a different time of the day.



N 3 70771 14364 1

Lot :

Exp. :

Over Coding Template

RISEDRONATE SODIUM

risedronate sodium tablet, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1436
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RISEDRONATE SODIUM ANHYDROUS (UNII: OFG5EXG60L) (RISEDRONIC ACID - UNII:KM2Z91756Z)	RISEDRONATE SODIUM ANHYDROUS	35 mg

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	YELLOW (YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1436-4	1 in 1 CARTON	04/10/2019	
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA203822	04/10/2019	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1436) , MANUFACTURE(70771-1436)

Revised: 9/2023 Zydus Lifesciences Limited