XL-DOL - acetaminophen tablet
Selder, S.A. de C.V.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients (in each tablet)
Acetaminophen USP 500 mg

Purpose
Analgesic

Uses temporarily relieves minor aches and pains associated with: •common cold •headaches •toothache •muscular aches •minor pain from arthritis •reduce fever

Warning: Do not use: •with any other product containing acetaminophen •for more than 10 days for pain, unless directed by a doctor •for more than 3 days for fever, unless directed by a doctor

Stop using the product and ask a doctor if •symptoms do not improve •new symptoms occur •pain or fever persist or gets worse •redness or swelling is present

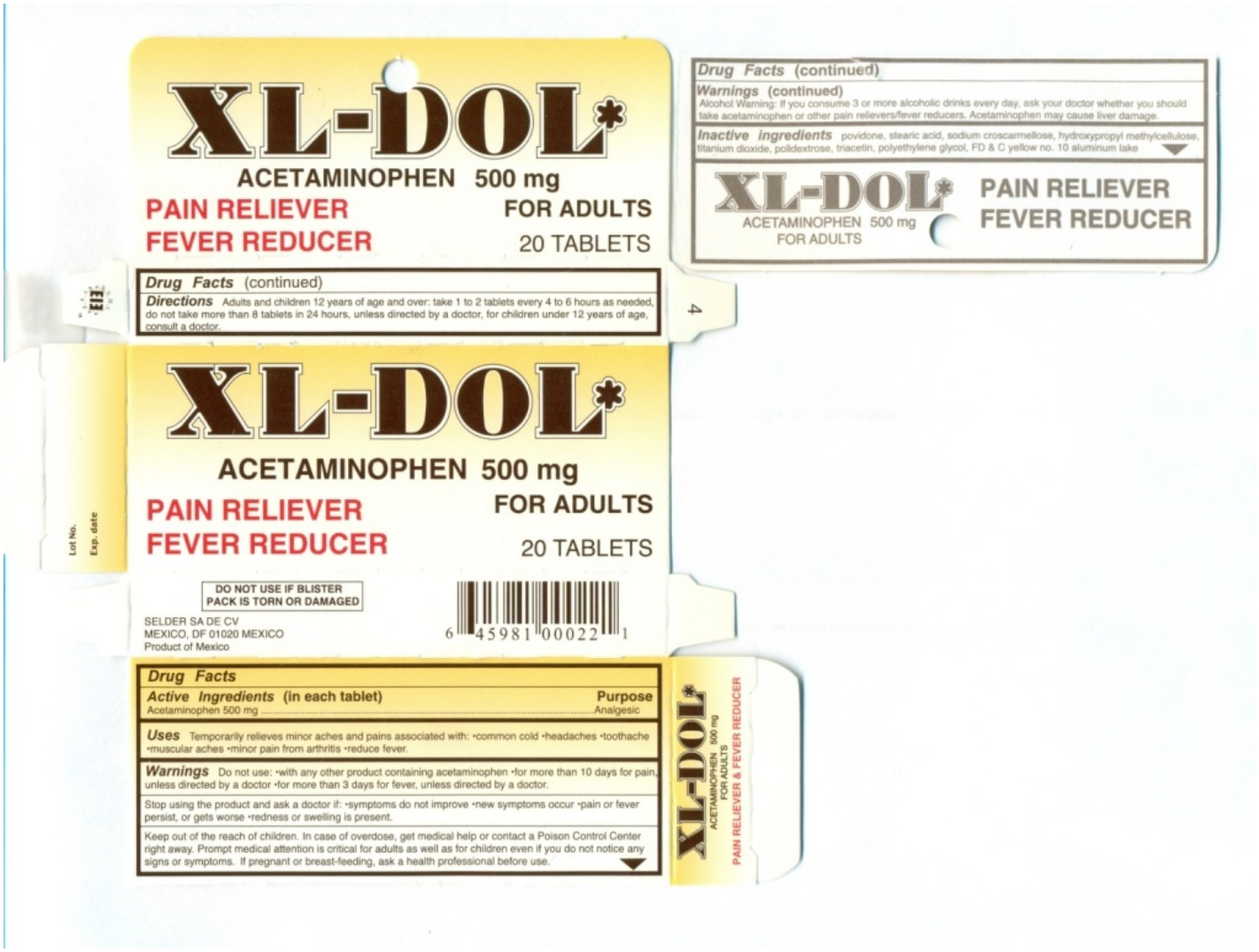
Keep out the reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms. If pregnant or breast-feeding, ask a health professional before use.

***Alcohol Warning*:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Inactive Ingredients povidone, stearic acid, sodium croscarmellose, hydroxypropylmethylcellulose, titanium dioxide, polydextrose, triacetin, polyethylene glycol, DC Yellow No.10

Directions Adults and children 12 years and over: take 1 to 2 tablets every 4 to 6 hours as needed, do not take more than 8 tablets in 24 hours unless directed by a doctor, for children under 12 years of age consult a doctor.

Package Label



XL-DOL

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63654-500
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
TRIACETIN (UNII: XHX3C3X673)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	yellow (light yellow)	**Score**	2 pieces
Shape	ROUND (Tablet)	**Size**	6mm
Flavor		**Imprint Code**	XL;DOL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63654-500-20	20 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/15/2011	

Labeler - Selder, S.A. de C.V. (824413629)

Establishment

Name	Address	ID/FEI	Business Operations
Selder, S.A. de C.V.		824413629	manufacture

Revised: 10/2011 Selder, S.A. de C.V.