ADULT LOW DOSE ASPIRIN- aspirin tablet, delayed release
Aidarex Pharmaceuticals LLC

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 Ingredient (in each tablet):

Aspirin 81mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose
Pain reliever

- for the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product may not provide fast relief of headache or other symptoms needing immediate relief.
- ask your doctor about other uses for this product.

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this products. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:
- hives
- asthma (wheezing)
- facial swelling
- shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you
- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use if
you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer

Ask a doctor before use if
- the stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease

- you have asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are taking a prescription drug for:
- gout
- diabetes
- arthritis

Stop use and ask a doctor if:
- you experience any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better
- allergic reaction occurs
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs of a serious condition.

If pregnant or breast-feeding,
ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.
In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions:
- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours while symptoms persist. Do not to exceed 48 tablets in 24 hors or as directed by a physician
- children under 12 years: consult a physician

Other information
- **Tamper Evident: Do not use if safety seal under cap is broken or missing**
- store at room temperature (15°-30°C)
- avoid excess heat and moisture

Inactive ingredients: crosscarmellose Sodium, D&C yellow# 10 Lake, FD&C yellow #6, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide.

Questions?
Adverse drug event call: (866) 562-2756

ADULT LOW DOSE ASPIRIN

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:33261-152(NDC:16103-356)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	YELLOW (YELLOW COLOR)	**Score**	no score
Shape	ROUND (ROUND TABLET)	**Size**	8mm
Flavor		**Imprint Code**	PH023
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33261-152-00	100 in 1 BOTTLE, PLASTIC		
2	NDC:33261-152-09	1 in 1 CARTON		
2	NDC:33261-152-30	30 in 1 BOTTLE, PLASTIC		
3	NDC:33261-152-60	60 in 1 BOTTLE, PLASTIC		
4	NDC:33261-152-90	90 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	01/12/2007	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 9/2012 Aidarex Pharmaceuticals LLC