ACETAMINOPHEN- acetaminophen tablet
H.J. Harkins Company, Inc.

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.

0002-10,00,14,15,20,24,25,30,40,42,45,50,90

Acetaminophen 500 mg

Pain Reliever/Fever Reducer

- temporarily relieves minor aches and pains
- temporarily reduces fever

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take

more than 8 tablets in 24 hours, which is the maximum daily amount
with other drugs containing acetaminophen
3 or more alcoholic drinks every day while using this product

Do not use

with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

liver disease.

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

pain gets worse or lasts more than 10 days
fever gets worse or lasts more than 3 days
new symptom occur
redness or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Overdose Warning:

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

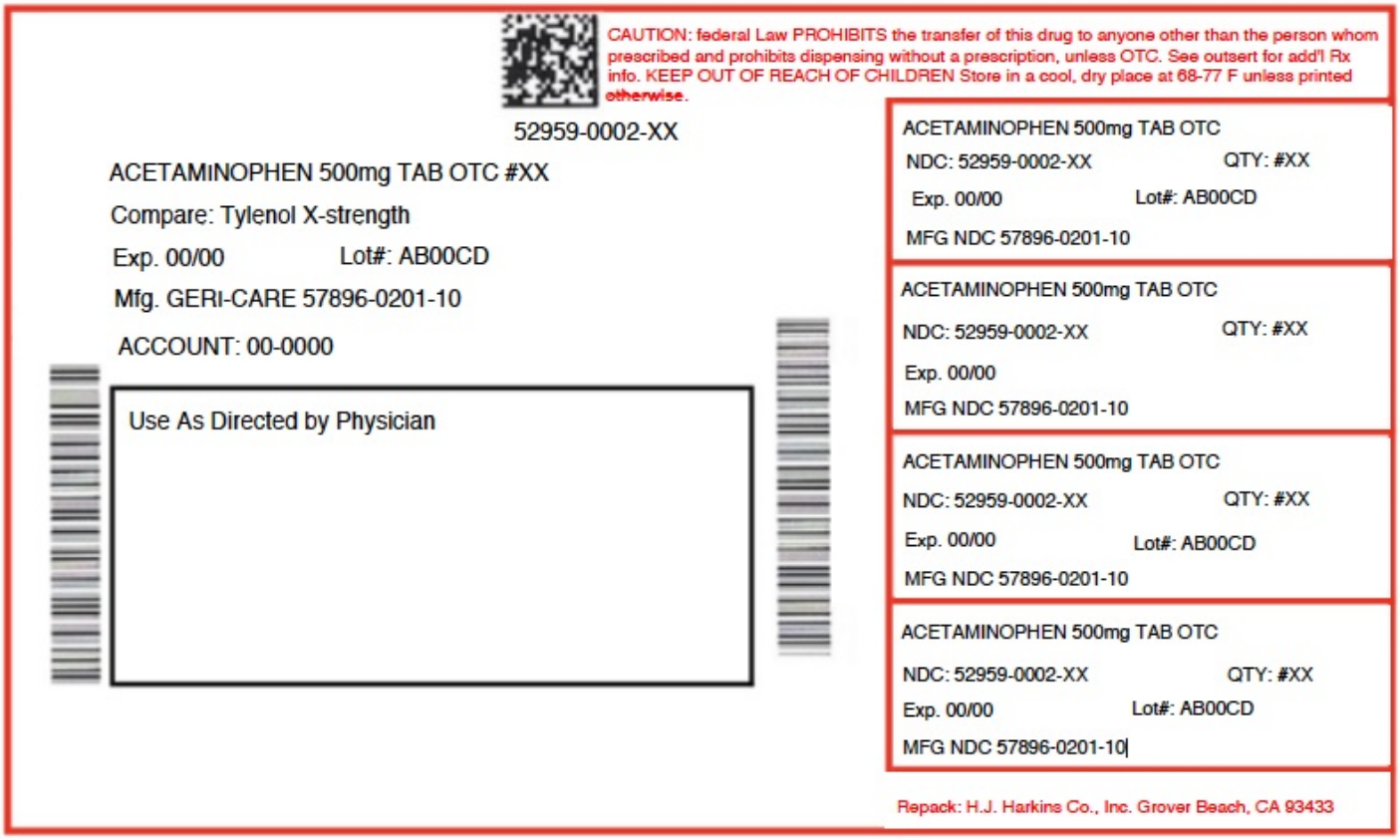
Keep out of reach of children.

- do not take more than directed
- adults and children 12 years and over: take 1-2 tablets every 4-6 hours, as needed; not more than 8 tablets in 24 hours
- children under 12 years: do not use

povidone, sodium starch glycolate, starch, stearic acid. May also contain: crospovidone, methylparaben and propylparaben

KEEP OUT OF REACH OF CHILDREN

- **TAMPER EVIDENT: Do not use if imprinted seal under cap is missing or broken.**
- **store at 20°C-25°C (68°F-77°F)**
- **for institutional use only**



ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52959-002
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**
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	M2A457344
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-002-10	10 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	
2	NDC:52959-002-14	14 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	
3	NDC:52959-002-15	15 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	
4	NDC:52959-002-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	
5	NDC:52959-002-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	
6	NDC:52959-002-25	25 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	
7	NDC:52959-002-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	
8	NDC:52959-002-40	40 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	
9	NDC:52959-002-42	42 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	
10	NDC:52959-002-45	45 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	
11	NDC:52959-002-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	
12	NDC:52959-002-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/08/2001	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/08/2001	

Labeler - H.J. Harkins Company, Inc. (147681894)

Establishment

Name	Address	ID/FEI	Business Operations
H.J. Harkins Company, Inc.		147681894	manufacture(52959-002) , relabel(52959-002) , repack(52959-002)

Revised: 9/2018 H.J. Harkins Company, Inc.