

**ACETAMINOPHEN- acetaminophen tablet**  
**Aphena Pharma Solutions - Tennessee, 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.*

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**ACETAMINOPHEN 325 mg**

**Active Ingredient**

**(in each tablet)**

Acetaminophen 325 mg

**Purpose**

Pain Reliever / Fever Reducer

**Uses**

temporarily reduces fever and relieves minor aches and pains caused by

- common cold
- headache
- toothache
- backache
- muscular aches
- minor pain of arthritis
- premenstrual and menstrual cramps

**Warnings**

**Liver warning:** this product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 12 tablets in 24 hours, which is the maximum daily amount
- child takes more than 5 tablets in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

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

**Ask a doctor before use if the user has** liver disease

**Ask a doctor or pharmacist before use if the user is** taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- adult's pain gets worse or lasts more than 10 days
- child's pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms appear

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

**Overdose warning:** Taking more than the recommended dose may cause liver damage. In case of

overdose contact Poison Control Center right away. Quick medical attention is critical for adults as well as children even if you do not notice any signs of symptoms.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

**Directions**

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adults and children 12 years and over	2 tablets every 4 to 6 hours while symptoms last, not more than 10 tablets in 24 hours. Do not use more than 10 days unless directed by doctor
children 6 to 11 years	1 tablet every 4-6 hours while symptoms last, not more than 5 tablets in 24 hours. Do not use more than 5 days unless directed by doctor
children under 6 years	ask a doctor

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**Other Information**

store at 15-30 °C (59-86 °F)

**Inactive Ingredients**

polyvinylpyrrolidone, pregelatinized corn starch, sodium starch glycolate, stearic acid

**Questions or Comments**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday**

**Repackaging Information**

Please reference the *How Supplied* section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

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<b>Count</b>	<b>325 mg</b>
100	71610-238-65

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Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:

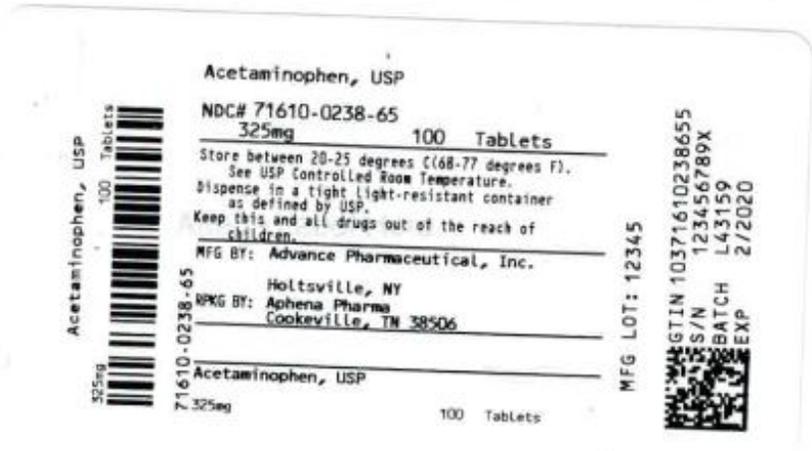


Cookeville, TN 38506

20190226JH

**PRINCIPAL DISPLAY PANEL - 325 mg**

NDC 71610-238 - Acetaminophen, USP 325 mg Tablets - Rx Only



**ACETAMINOPHEN**

acetaminophen tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71610-238(NDC:54738-548)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	AP;012

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-238-65	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/13/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/01/2015	

**Labeler** - Aphenia Pharma Solutions - Tennessee, LLC (128385585)**Establishment**

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-238)

Revised: 2/2019

Aphenia Pharma Solutions - Tennessee, LLC