附件一

	部授食字第1041400588A號公告	建議(綜合感冒劑指示藥品)	理由	民101年7月5日指示藥品基準-綜合感冒劑	建議(解熱鎮痛劑指示藥品)	理由	民95年5月15日指示藥品基準　解熱鎮痛劑
（一）肝毒性：	1. 使用acetaminophen (paracetamol)曾有發生急性肝衰竭的案例，並可能導致肝臟移植及死亡。大部份發生肝臟損害之病例係因使用超過每日4,000毫克的acetaminophen所致，且多涉及使用超過一種以上含acetaminophen成分之藥品。	不刊載	產品標示遵循指示藥品基準，已刊載相同語意之字句	[警語]酒精警語：不得併服含酒精飲料，因為Acetaminophe（Paracetamol）可能造成肝損害。（含Acetaminophen（Paracetamol）之製劑） [用法用量]「一日3至4次」或「每4-6小時一次，24小時不可超過○次」，擇一刊載。 [注意事項] 勿超過建議劑量，若有不適情況產生，應立即停藥就醫。 [注意事項] 除非有醫師藥師藥劑生指示，服用本藥時不得併服其他藥品。 [警語]除非有醫師藥師藥劑生指示，不得併用其他綜合感冒藥、鎮咳祛痰藥、鼻炎藥物或抗過敏藥及解熱鎮痛等藥物。	刊載	無	無
	2. 過量服用acetaminophen可能是因想要獲得更大的疼痛緩解效果，或是在不知道的情況下同時使用了其他同樣含有acetaminophen成分之藥品，因而造成用藥過量。	不刊載	產品標示遵循指示藥品基準，已刊載相同語意之字句	[注意事項] 除非有醫師藥師藥劑生指示，服用本藥時不得併服其他藥品。 [警語]除非有醫師藥師藥劑生指示，不得併用其他綜合感冒藥、鎮咳祛痰藥、鼻炎藥物或抗過敏藥及解熱鎮痛等藥物。	不刊載	資訊重複，因第3點告知消費者不可同時使用超過一種以上含有acetaminophen成分之藥品。	無
	3. 有潛在肝臟疾病的病人，以及於使用acetaminophen期間喝酒者，有較高發生急性肝衰竭的風險。	不刊載	產品標示遵循指示藥品基準，已刊載相同語意之字句	[警語]患有肝、腎疾病或其他重大疾病之患者，服用本藥前，應先請教醫師藥師藥劑生。	刊載	無	無
	3. 醫療人員應囑咐病人，病人亦應注意藥品的標示中是否含有acetaminophen或paracetamol成分，不可同時使用超過一種以上含有acetaminophen成分之藥品。	不刊載	產品標示遵循指示藥品基準，已刊載相同語意之字句	[注意事項] 除非有醫師藥師藥劑生指示，服用本藥時不得併服其他藥品。 [警語]除非有醫師藥師藥劑生指示，不得併用其他綜合感冒藥、鎮咳祛痰藥、鼻炎藥物或抗過敏藥及解熱鎮痛等藥物。	修改為「病人應注意藥品的標示中是否含有acetaminophen或paracetamol成分，不可同時使用超過一種以上含有acetaminophen成分之藥品。」	指示藥品之仿單閱讀對象為民眾，非醫療人員，建議刪除「醫療人員應囑咐病人」字句	無
	3. 如果一天誤服超過4,000毫克的acetaminophen，即使並未感覺不適，也應立即就醫。	刊載	無	無	刊載	無	無
（二）與酒精併用：	不得併服含酒精飲料，因為acetaminophen可能造成肝損害。	不刊載	產品標示遵循指示藥品基準，已刊載相同語意之字句	[注意事項]不得併服含酒精飲料。 [警語]酒精警語：不得併服含酒精飲料，因為Acetaminophe（Paracetamol）可能造成肝損害。（含Acetaminophen（Paracetamol）之製劑）	不刊載	產品標示遵循指示藥品基準，已刊載相同語意之字句	[注意事項]不得併服含酒精飲料。 [警語]酒精警語：若每日喝三杯或更多之酒精性飲料，請詢問醫師是否能服用本藥，因為Acetaminophen可能造成肝損害（含Acetaminophen（Paracetamol）之製劑）
	慢性重度酒精濫用者亦可能會因過度使用acetaminophen而增加肝毒性危險，本品不應與酒精併用。	修改為「慢性重度酒精濫用者亦可能會因過度使用acetaminophen而增加肝毒性危險。」	字句重複，建議刪除「本品不應與酒精併用」字句	無	修改為「慢性重度酒精濫用者亦可能會因過度使用acetaminophen而增加肝毒性危險。」	字句重複，建議刪除「本品不應與酒精併用」字句	無
（三）過量：	1. 服用過量acetaminophen會在服藥24小時內看到初期症狀，可能包括：胃腸道不適、厭食、噁心、嘔吐、不適、蒼白及出汗。	刊載	無	無	刊載	無	無
	2. 本品單次或多次過量使用有潛在的藥物成癮或濫用之可能，情況允許下，建議諮詢適當的專家。	刊載	無	無	刊載	無	無
	3. Acetaminophen過量最嚴重之不良反應為致命性之肝臟壞死。亦可能發生腎小管壞死，低血糖昏迷以及凝血異常之不良反應。用藥過量之肝毒性早期症狀可能包括：噁心、嘔吐、出汗和全身不…	刊載	無	無	刊載	無	無
	3. 肝毒性的臨床及實驗室證據可能要等到攝入後48~72小時才明顯可見。	修改為「肝毒性的臨床證據可能要等到攝入後48~72小時才明顯可見。」	指示藥品之仿單閱讀對象為民眾，非醫療人員，建議刪除「及實驗室」字句	無	修改為「肝毒性的臨床證據可能要等到攝入後48~72小時才明顯可見。」	指示藥品之仿單閱讀對象為民眾，非醫療人員，建議刪除「及實驗室」字句	無
（四）過敏/過敏性反應：	上市後曾有發生與使用acetaminophen相關之過敏及過敏性反應的報告。臨床表徵包括臉、口及喉嚨腫脹、呼吸窘迫、蕁麻疹、皮疹、搔癢以及嘔吐。偶有發生危及生命並須緊急送醫治療之過敏性反應的案例。	刊載	無	無	刊載	無	無
	醫療人員應提醒病人，如果發生這些症狀，應立即停藥並就醫治療。	修改為「如果發生這些症狀，應立即停藥並就醫治療。」	指示藥品之仿單閱讀對象為民眾，非醫療人員，建議刪除「醫療人員應提醒病人」字句	無	修改為「如果發生這些症狀，應立即停藥並就醫治療。」	指示藥品之仿單閱讀對象為民眾，非醫療人員，建議刪除「醫療人員應提醒病人」字句	無
	曾對acetaminophen過敏的病人，亦應主動告知醫療人員，切勿使用含該成分之藥品。	不刊載	產品標示遵循指示藥品基準，已刊載相同語意之字句	[警語]除非有醫師藥師藥劑生指示，曾經因本藥引起過敏症狀者不得使用。	不刊載	產品標示遵循指示藥品基準，已刊載相同語意之字句	[警語]除非有醫師藥師藥劑生指示，曾經因藥物引起過敏症狀者不得使用。
（五）嚴重皮膚反應：	使用acetaminophen的病人中，曾有少數發生嚴重且可能致命之皮膚反應的報告，如急性全身發疹性膿皰病(Acute Generalized Exanthematous Pustulosis, AGEP)、史蒂文生氏-強生症候群(Stevens - Johnson Syndrome, SJS)和毒性表皮壞死溶解症(Toxic Epidermal Necrolysis, TEN)。	刊載	無	無	刊載	無	無
	病人應瞭解並被告知嚴重皮膚反應的症狀，以及出現皮疹或其他過敏症狀時，應停止使用本藥。	修改為「出現皮疹或其他過敏症狀時，應停止使用本藥。」	指示藥品之仿單閱讀對象為民眾，非醫療人員，且字句重複，建議刪除「病人應瞭解並被告知嚴重皮膚反應的症狀，以及」字句	無	修改為「出現皮疹或其他過敏症狀時，應停止使用本藥。」	指示藥品之仿單閱讀對象為民眾，非醫療人員，且字句重複，建議刪除「病人應瞭解並被告知嚴重皮膚反應的症狀，以及」字句	無

附件二

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HHS U.S. Department of Health and Human Services
FDA

U.S. Food and Drug Administration

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FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure

Safety Announcement

[1-13-2011] The U.S. Food and Drug Administration (FDA) is asking drug manufacturers to limit the strength of acetaminophen in prescription drug products, which are predominantly combinations of acetaminophen and opioids. This action will limit the amount of acetaminophen in these products to 325 mg per tablet, capsule, or other dosage unit, making these products safer for patients.

In addition, a *Boxed Warning* highlighting the potential for severe liver injury and a *Warning* highlighting the potential for allergic reactions (e.g., swelling of the face, mouth, and throat, difficulty breathing, itching, or rash) are being added to the label of all prescription drug products that contain acetaminophen.

These actions will help to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen.

Acetaminophen is widely and effectively used in both prescription and over-the-counter (OTC) products to reduce pain and fever. It is one of the most commonly-used drugs in the United States. Examples of prescription products that contain acetaminophen include hydrocodone with acetaminophen (Vicodin, Lortab), and oxycodone with acetaminophen (Tylox, Percocet).

OTC products containing acetaminophen (e.g., Tylenol) are not affected by this action. Information about the potential for liver injury is already required on the label for OTC products containing acetaminophen. FDA is continuing to evaluate ways to reduce the risk of acetaminophen related liver injury from OTC products. Additional safety measures relating to OTC acetaminophen products will be taken through separate action, such as a rulemaking as part of the ongoing OTC monograph proceeding for internal analgesic drug products.

Additional Information for Patients

- Acetaminophen-containing prescription products are safe and effective when used as directed, though all medications carry some risks.
- Do not stop taking your prescription pain medicine unless told to do so by your healthcare professional.
- Carefully read all labels for prescription and OTC medicines and ask the pharmacist if your prescription pain medicine contains acetaminophen.
- Do not take more than one product that contains acetaminophen at any given time.
- Do not take more of an acetaminophen-containing medicine than directed.
- Do not drink alcohol when taking medicines that contain acetaminophen.
- Stop taking your medication and seek medical help immediately if you:
    - Think you have taken more acetaminophen than directed or
    - Experience allergic reactions such as swelling of the face, mouth, and throat, difficulty breathing, itching, or rash.
- Report side effects to FDA's MedWatch program using the information in the "Contact Us" box at the bottom of the page.

Additional Information for Healthcare Professionals

The maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit will be limited to 325 mg. However, the total number of tablets or capsules that may be prescribed and the time intervals at which they may be prescribed will not change as a result of the lower amount of acetaminophen. For example, for a product that previously contained 500 mg of acetaminophen with an opioid and was prescribed as 1-2 tablets every 4-6 hours, once reformulated to contain 325 mg of acetaminophen, the dosing instructions can remain unchanged.

- Advise patients not to exceed the acetaminophen maximum total daily dose (4 grams/day).
- Severe liver injury, including cases of acute liver failure resulting in liver transplant and death, has been reported with the use of acetaminophen.

- Educate patients about the importance of reading all prescription and OTC labels to ensure they are not taking multiple acetaminophen-containing products.
- Advise patients not to drink alcohol while taking acetaminophen-containing medications.
- Rare cases of anaphylaxis and other hypersensitivity reactions have occurred with the use of acetaminophen.
- Advise patients to seek medical help immediately if they have taken more acetaminophen than directed or experience swelling of the face, mouth, and throat, difficulty breathing, itching, and rash.
- Report adverse events to FDA's MedWatch program using the information in the "Contact Us" box at the bottom of the page.

Data Summary and Discussion

A number of studies have tried to answer the question of how common liver injury is in relation to the use of acetaminophen. Although many questions remain about the full scope of the problem, the following examples indicate what is known about the extent of liver failure cases reported in the medical literature and clearly indicates a reason for concern:

- From 1998 to 2003, acetaminophen was the leading cause of acute liver failure in the United States, with 48% of acetaminophen-related cases (131 of 275) associated with accidental overdose.[1]
- A 2007 Centers for Disease Control and Prevention (CDC) population-based report estimates that, nationally, there are 1600 cases of acute liver failure (ALF) each year (all causes). Acetaminophen-related ALF was the most common etiology.[2]
- Summarizing data from three different surveillance systems, there were an estimated 56,000 emergency room visits, 26,000 hospitalizations, and 458 deaths related to acetaminophen-associated overdoses per year during the 1990-1998 period.[3]
- In a study that combined data from 22 specialty medical centers in the United States, acetaminophen-related liver injury was the leading cause of ALF for the years 1998 through 2003.[1] This study also found that a high percentage of cases of liver injury due to acetaminophen were related to unintentional overdose, in which the patient mistakenly took too much acetaminophen. This finding was confirmed in a later study (2007).[2] Many other cases of acute liver injury are caused by intentional overdoses of acetaminophen (i.e., associated with self-harm).
- Across various studies, consumers were found to have taken more than the recommended dose when using an OTC product, a prescription product, or both. The Toxic Exposure Surveillance System (TESS), now named the National Poison Data System (NPDS), which captures data from calls to 61 poison control centers, provides additional data on acetaminophen overdose and serious injury. In 2005, TESS showed that calls about poisoning cases that resulted in major injury numbered 1,187 for OTC single-ingredient products, 653 for OTC combination products, and 1,470 for prescription-opioid combination products.[4]

The risk of liver injury associated with the use of acetaminophen was discussed at the Joint Meeting of the FDA Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and Anesthetic and Life Support Drugs Advisory Committee, held on June 29-30, 2009 (for complete safety reviews and background information discussed at this meeting).

The Advisory Committee recommended a range of additional regulatory actions such as adding a boxed warning to prescription acetaminophen products, withdrawing prescription combination products from the market, or reducing the amount of acetaminophen in each dosage unit. FDA considered the Committee's advice for OTC products when deciding to limit the amount of acetaminophen per dosage unit in prescription products.

By limiting the maximum amount of acetaminophen in prescription products to 325 mg per dosage unit, patients will be less likely to overdose on acetaminophen if they mistakenly take too many doses of acetaminophen-containing products.

For more information on safety considerations for acetaminophen, visit the following link on the FDA web

site: Acetaminophen Information

Table

List of Marketed Acetaminophen-Containing Prescription Products (products affected by the new dosage unit limits are in italics)

1-14-2014: This list was accurate at the time this Drug Safety Communication was published on 1-13-2011; however, it is no longer accurate. FDA intends to publish a new list once the withdrawals currently in process of combination drug products containing more than 325 mg acetaminophen per dosage unit are finalized.

The label may not spell out the whole word or may have an abbreviation, such as “APAP, AC, Acetaminophn, Acetaminoph, Acetaminop, Acetamin or Acetam. “

Brand Name	Generic Name	Dosage Form	Strength
No Current Brand Name	Acetaminophen; Aspirin; Codeine Phosphate	Capsule; Oral	150mg; 180mg; 30mg
No Current Brand Name	*Acetaminophen; Caffeine; Dihydrocodeine Bitartrate*	*Capsule; Oral*	*356.4mg; 30mg; 16mg*
No Current Brand Name	*Acetaminophen; Caffeine; Dihydrocodeine Bitartrate*	*Tablet; Oral*	*712.8mg; 60mg; 32mg*
No Current Brand Name	Acetaminophen; Codeine Phosphate	Solution; Oral	120mg/ 5mL; 12mg/ 5mL
No Current Brand Name	Acetaminophen; Codeine Phosphate	Tablet; Oral	300mg; 15mg
No Current Brand Name	*Acetaminophen; Codeine Phosphate*	*Tablet; Oral*	*650mg; 30mg*
No Current Brand Name	*Acetaminophen; Codeine Phosphate*	*Tablet; Oral*	*650mg; 60mg*
Capital and Codeine	Acetaminophen; Codeine Phosphate	Suspension; Oral	120mg/ 5mL; 12mg/ 5mL
Tylenol W/ Codeine No. 3	Acetaminophen; Codeine Phosphate	Tablet; Oral	300mg; 30mg
Tylenol W/ Codeine No. 4	Acetaminophen; Codeine Phosphate	Tablet; Oral	300mg; 60mg
No Current Brand Name	*Acetaminophen; Butalbital; Caffeine*	*Tablet; Oral*	*500mg; 50mg; 40mg*
Esgic-Plus	*Acetaminophen; Butalbital; Caffeine*	*Tablet; Oral*	*500mg; 50mg; 40mg*
No Current Brand Name	*Acetaminophen; Butalbital; Caffeine*	*Capsule; Oral*	*500mg; 50mg; 40mg*
Esgic-Plus	*Acetaminophen; Butalbital; Caffeine*	*Capsule; Oral*	*500mg; 50mg; 40mg*
No Current Brand Name	Acetaminophen; Butalbital; Caffeine	Tablet; Oral	325mg; 50mg; 40mg
Fioricet	Acetaminophen; Butalbital; Caffeine	Tablet; Oral	325mg; 50mg; 40mg
No Current Brand Name	Acetaminophen; Butalbital; Caffeine; Codeine Phosphate	Capsule; Oral	325mg; 50mg; 40mg; 30mg
Fioricet w/ codeine	Acetaminophen; Butalbital; Caffeine; Codeine Phosphate	Capsule; Oral	325mg; 50mg; 40mg; 30mg
Phrenilin with Caffeine and Codeine	Acetaminophen; Butalbital; Caffeine; Codeine Phosphate	Capsule; Oral	325mg; 50mg; 40mg; 30mg
Anexsia	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*500mg; 5mg*
Anexsia	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*750mg; 10mg*

Anexsia 5/ 325	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	325mg; 5mg
Anexsia 7.5/ 325	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	325mg; 7.5mg
Anexsia 7.5/ 650	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*650mg; 7.5mg*
Co-Gesic	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*500mg; 5mg*
No Current Brand Name	*Acetaminophen; Hydrocodone Bitartrate*	*Capsule; Oral*	*500mg; 5mg*
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Solution; Oral	325mg/ 15mL; 10mg/ 15mL
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Solution; Oral	325mg/ 15mL; 7.5mg/ 15mL
No Current Brand Name	*Acetaminophen; Hydrocodone Bitartrate*	*Solution; Oral*	*500mg/ 15mL; 10mg/ 15mL*
No Current Brand Name	*Acetaminophen; Hydrocodone Bitartrate*	*Solution; Oral*	*500mg/ 15mL; 7.5mg/ 15mL*
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	300mg; 10mg
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	300mg; 5mg
No Current Brand Name	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	300mg; 7.5mg
No Current Brand Name	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*500mg; 2.5mg*
No Current Brand Name	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*500mg; 7.5mg*
No Current Brand Name	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*650mg; 10mg*
Lortab	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*500mg; 10mg*
Lortab	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*500mg; 5mg*
Norco	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	325mg; 10mg
Norco	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	325mg; 5mg
Norco	Acetaminophen; Hydrocodone Bitartrate	Tablet; Oral	325mg; 7.5mg
Vicodin	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*500mg; 5mg*
Vicodin Es	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*750mg; 7.5mg*
Vicodin Hp	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*660mg; 10mg*
Zydone	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*400mg; 10mg*
Zydone	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*400mg; 5mg*
Zydone	*Acetaminophen; Hydrocodone Bitartrate*	*Tablet; Oral*	*400mg; 7.5mg*
Oxycet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 5mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	300mg; 10mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	300mg; 2.5mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	300mg; 5mg
No Current Brand Name	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	300mg; 7.5mg
No Current Brand Name	*Acetaminophen; Oxycodone Hydrochloride*	*Tablet; Oral*	*400mg; 10mg*
No Current Brand Name	*Acetaminophen; Oxycodone Hydrochloride*	*Tablet; Oral*	*400mg; 2.5mg*
No Current Brand Name	*Acetaminophen; Oxycodone Hydrochloride*	*Tablet; Oral*	*400mg; 5mg*
No Current Brand Name	*Acetaminophen; Oxycodone Hydrochloride*	*Tablet; Oral*	*400mg; 7.5mg*
No Current Brand Name	*Acetaminophen; Oxycodone Hydrochloride*	*Tablet; Oral*	*500mg; 10mg*
Percocet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 10mg
Percocet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 2.5mg

Percocet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 5mg
Percocet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 7.5mg
Percocet	*Acetaminophen; Oxycodone Hydrochloride*	*Tablet; Oral*	*500mg; 7.5mg*
Percocet	*Acetaminophen; Oxycodone Hydrochloride*	*Tablet; Oral*	*650mg; 10mg*
Roxicet	Acetaminophen; Oxycodone Hydrochloride	Solution; Oral	325mg/ 5mL; 5mg/ 5mL
Roxicet	Acetaminophen; Oxycodone Hydrochloride	Tablet; Oral	325mg; 5mg
Roxicet 5/ 500	*Acetaminophen; Oxycodone Hydrochloride*	*Tablet; Oral*	*500mg; 5mg*
Roxilox	*Acetaminophen; Oxycodone Hydrochloride*	*Capsule; Oral*	*500mg; 5mg*
Tylox	*Acetaminophen; Oxycodone Hydrochloride*	*Capsule; Oral*	*500mg; 5mg*
Talacen	*Acetaminophen; Pentazocine Hydrochloride*	*Tablet; Oral*	*650mg; EQ 25mg BASE*
Ultracet	Acetaminophen; Tramadol Hydrochloride	Tablet; Oral	325mg; 37.5mg

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Related Information

- Acetaminophen Information
- FDA limits acetaminophen in prescription combination products; requires liver toxicity warnings [ARCHIVED]
  Press Release - 1/13/2011
- Questions and Answers about Oral Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit
  1/13/2011
- 2009 Meeting Materials, Drug Safety and Risk Management Advisory Committee
- FDA Drug Safety Podcast for Healthcare Professionals: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure [ARCHIVED]

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附件三

含 Acetaminophen 之綜合感冒劑（已遵循指示藥品基準-綜合感冒劑刊載者）依「部授食字第 1041400588A 號公告」應再刊載：

(一) 肝毒性：

- 如果一天誤服超過 4,000 毫克的 acetaminophen，即使並未感覺不適，也應立即就醫。

（二）與酒精併用：

- 慢性重度酒精濫用者亦可能會因過度使用 acetaminophen 而增加肝毒性危險。

（三）過量：

- 服用過量 acetaminophen 會在服藥 24 小時內看到初期症狀，可能包括：胃腸道不適、厭食、噁心、嘔吐、不適、蒼白及出汗。
- 本品單次或多次過量使用有潛在的藥物成癮或濫用之可能，情況允許下，建議諮詢適當的專家。
- Acetaminophen 過量最嚴重之不良反應為致命性之肝臟壞死。亦可能發生腎小管壞死，低血糖昏迷以及凝血異常之不良反應。用藥過量之肝毒性早期症狀可能包括：噁心、嘔吐、出汗和全身不適。
- 肝毒性的臨床證據可能要等到攝入後 48~72 小時才明顯可見。

（四）過敏/過敏性反應：

- 上市後曾有發生與使用 acetaminophen 相關之過敏及過敏性反應的報告。臨床表徵包括臉、口及喉嚨腫脹、呼吸窘迫、蕁麻疹、皮疹、搔癢以及嘔吐。偶有發生危及生命並須緊急送醫治療之過敏性反應的案例。
- 如果發生這些症狀，應立即停藥並就醫治療。

（五）嚴重皮膚反應：

- 使用 acetaminophen 的病人中，曾有少數發生嚴重且可能致命之皮膚反應的報告，如急性全身發疹性膿皰病(Acute Generalized Exanthematous Pustulosis, AGEP)、史蒂文生氏-強生症候群(Stevens - Johnson Syndrome, SJS)和毒性表皮壞死溶解症(Toxic Epidermal Necrolysis, TEN)。
- 出現皮疹或其他過敏症狀時，應停止使用本藥。

附件四

含 Acetaminophen 之解熱鎮痛劑（已遵循指示藥品基準-綜合感冒劑刊載者）依「部授食字第 1041400588A 號公告」應再刊載：

(一) 肝毒性：

- 使用 acetaminophen (paracetamol)曾有發生急性肝衰竭的案例，並可能導致肝臟移植及死亡。大部份發生肝臟損害之病例係因使用超過每日 4,000 毫克的 acetaminophen 所致，且多涉及使用超過一種以上含 acetaminophen 成分之藥品。
- 有潛在肝臟疾病的病人，以及於使用 acetaminophen 期間喝酒者，有較高發生急性肝衰竭的風險。
- 病人應注意藥品的標示中是否含有 acetaminophen 或 paracetamol 成分，不可同時使用超過一種以上含有 acetaminophen 成分之藥品。
- 如果一天誤服超過 4,000 毫克的 acetaminophen，即使並未感覺不適，也應立即就醫。

（二）與酒精併用：

- 慢性重度酒精濫用者亦可能會因過度使用 acetaminophen 而增加肝毒性危險。

（三）過量：

- 服用過量 acetaminophen 會在服藥 24 小時內看到初期症狀，可能包括：胃腸道不適、厭食、噁心、嘔吐、不適、蒼白及出汗。
- 本品單次或多次過量使用有潛在的藥物成癮或濫用之可能，情況允許下，建議諮詢適當的專家。
- Acetaminophen 過量最嚴重之不良反應為致命性之肝臟壞死。亦可能發生腎小管壞死，低血糖昏迷以及凝血異常之不良反應。用藥過量之肝毒性早期症狀可能包括：噁心、嘔吐、出汗和全身不適。
- 肝毒性的臨床證據可能要等到攝入後 48~72 小時才明顯可見。

（四）過敏/過敏性反應：

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- 如果發生這些症狀，應立即停藥並就醫治療。

（五）嚴重皮膚反應：

- 使用 acetaminophen 的病人中，曾有少數發生嚴重且可能致命之皮膚反應的報告，如急性全身發疹性膿皰病(Acute Generalized Exanthematous Pustulosis, AGEP)、史蒂文生氏-強生症候群(Stevens - Johnson Syndrome, SJS)和毒性表皮壞死溶解症(Toxic Epidermal Necrolysis, TEN)。
- 出現皮疹或其他過敏症狀時，應停止使用本藥。