
ACETAMINOPHEN PROTOCOL

The facility has adopted this protocol and shall practice for all residents of this facility.

The manufacturers of acetaminophen (APAP) recommend doses not to exceed 1000mg/dose or 4000mg/24 hours.

Nursing staff must be aware of the APAP consumption history of any resident for the previous 24 hours prior to administration of the next dose of APAP or a combination product containing APAP. This includes calculating the doses for routine and PRN orders

PROCEDURE

If the nurse determines the next dose would exceed the 4000mg ceiling, then prior to the administration of this dose, the physician must be notified to determine if:

1. There is an alternative medication which may be substituted for the APAP containing product.

Or,

2. The physician wishes the nurse to administer the additional APAP containing medication

And,

The nurse asks:

- a. For a Risk/Benefit statement of exceeding the 4000mg ceiling.

And,

- b. If it would be appropriate to order liver function tests (LFT) for potential APAP toxicity monitoring.

NOTE: If the physician refuses to order a LFT, the nurse would then need to obtain a risk/benefit statement from the physician.

Many prescription and over the counter (OTC) products contain APAP which must be considered when calculating the total daily dose.

ACETAMINOPHEN PER TABLET - MAX # OF TABS/24 HOURS

APAP mg/tab	325mg	500mg	650mg	750mg
MAX # tabs/day	12	8	6	5
MEDICATION	FIORICET	ANEXSIA	ANEXSIA	VICODIN ES
	NORCO	LORCET / LORTAB	DARVOCET	
	PERCOCET	TYLENOL 500mg	LORCET PLUS or 10/650	
	TYLENOL #2,#3,#4,PM	VICODIN	LORTAB 2.5/650	
	TYLENOL 325mg	WYGESIC	TALACEN	
	ULTRACET		VICODIN HP	

REFERENCES

SOM F329 Table I

- Daily doses greater than 4 grams/day from all sources (alone or as part of combination products) may increase risk of liver toxicity.
- For doses greater than the maximum recommended daily dose, documented assessment should reflect periodic monitoring of liver function and indicate that benefits outweigh risks.

The Medical Letter

- Toxicity is usually not seen until doses reach 6-7000mg per day.
- Chronic toxicity requires many days to months of routine dosing above 4000mg/day.

- A few days of dosing above 4000mg is not usually clinically significant enough to induce level damage.

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REFERENCES (continued)

In 1977, the Advisory Review Panel on OTC Internal Analgesic, Antipyretic and Antirheumatic Products concluded that acetaminophen was a safe and effective OTC analgesic when taken in an adult dosage of up to 1000 mg, not to exceed 4000 mg in 24 hours for no longer than ten days

Acetaminophen is generally well tolerated. It has milder gastrointestinal and renal effects than other NSAIDs. It may produce hepatic toxicity when taken in doses in excess of 4000 mg/day (the equivalent of eight extra-strength 500 mg tablets) for prolonged periods.

Rumack BH. Acetaminophen hepatotoxicity: the first 35 years. *J Toxicol Clin Toxicol.* 2002;40:3-20

Acetaminophen, at doses up to 4000 mg per day, is considered to be beneficial in the treatment of mild to moderate pain due to its favorable efficacy and safety profile [Amadio 1984].

Amadio P Jr. Peripherally acting analgesics. *Am J Med* 1984 Sep 10; 17-26

This same dose was reaffirmed in 1988, when FDA published the Tentative Final Monograph (TFM) for OTC Internal Analgesic, Antipyretic and Antirheumatic Products.

This is McNeil's background package on acetaminophen for the September 19, 2002 Nonprescription Drugs advisory Committee Meeting that was announced in the *Federal Register* of August 20, 2002. This submission provides data and an evidence-based assessment of acetaminophen efficacy and safety. The optimal effective adult analgesic dose of acetaminophen is 1000 mg every four to six hours, up to 4000 mg per 24 hours. This dosing frequency is supported by pharmacokinetic, clinical, and consumer use data.

McNeil Pharmaceutical Executive Summary 2002

ACETAMINOPHEN PROTOCOL - PROCEDURE

When administering any amount of Tylenol (acetaminophen, APAP) or combination product (see table below) the nurse must determine if the next dose would exceed the 4000mg ceiling.

If the dose would exceed the 4000mg for a 24 hour period, then prior to the administration of this dose, the nurse must contact the physician to determine if:

1. There is an alternative medication which may be substituted for the APAP containing product.

Or,

2. The physician wishes the nurse to administer the additional APAP containing medication.

And, the nurse then must ask the physician:

a. For a Risk/Benefit statement of exceeding the 4000mg ceiling.

And,

b. If it would be appropriate to order routine liver function tests (LFT) for potential APAP toxicity monitoring.

NOTE: If the physician refuses to order a LFT, the nurse would then need to obtain a risk/benefit statement from the physician.

Many prescription and over the counter (OTC) products contain APAP which must be considered when calculating the total daily dose.

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