

Harmony

*Packaging artwork and technical drawings
Approval Information*



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Ingredient used most by doctors

FOR FAST EFFECTIVE RELIEF OF HEADACHES, FEVER & EXTRA PAIN. CAN BE TAKEN ON EMPTY STOMACH.

Description
Each caplet contains Acetaminophen (Paracetamol) 500mg and Caffeine 65mg. It also contains Pregelatinized Starch, Povidone K-25, Calcium carbonate, Crospovidone, Blend of Sodium Parabens, Purified Water, Alginate Acid, Magnesium Stearate, Opadry White YS-1-7003 and Carnauba Wax.

Action
Panadol Extra Advance has been clinically proven as a fast effective analgesic and antipyretic which does not upset the stomach. Panadol Extra Advance contains caffeine which, when taken orally, acts as a mild central nervous system stimulant to aid in staying awake and to restore mental alertness in fatigued patients. It is frequently used as an adjunct to aid analgesia.

Indications
Panadol Extra Advance is indicated for the extra relief of painful disorders such as headache, migraine, toothache, sore throat, musculoskeletal pain, myalgias and dysmenorrhea. It is also indicated as an analgesic and antipyretic in conditions accompanied by pains and fever, such as the common cold and viral infections. Panadol Extra Advance is an effective analgesia after dental work and tooth extractions, and in teething.

Contraindications
Panadol Extra Advance is contraindicated in patients with a previous history of hypersensitivity to any of the constituents.

Precautions
This product contains paracetamol. Taking too much paracetamol can cause serious harm to your liver. Always read and follow the label. Keep this and all medications out of reach of children. If symptoms persist or you have been diagnosed with liver or kidney impairment, seek medical advice before taking this medicine. Please check with your doctor before use if you:

- are underweight or malnourished
- regularly drink alcohol
- You may need to avoid using this product altogether or limit the amount of paracetamol that you take.
- have a severe infection as this may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include:

- deep, rapid, difficult breathing
- feeling sick (nausea), being sick (vomiting)
- loss of appetite

Contact a doctor immediately if you get a combination of these symptoms.

This product is not recommended for use during pregnancy due to the possible increased risk of spontaneous abortion associated with caffeine consumption. Use during breast-feeding should be avoided. Caffeine in breast milk may potentially have a stimulating effect on breast fed infants but significant toxicity has not been observed.

Before taking this medicine, make sure you consult your doctor if you are taking Warfarin or similar medicines used to thin the blood. The anticoagulant effect of Warfarin and other Coumarins may be enhanced by prolonged regular daily use of Acetaminophen with increased risk of bleeding; occasional doses have no significant effect.

This medicine contains caffeine. Avoid drinking too many caffeine containing drinks (e.g. tea, coffee and caffeine-containing canned drinks) when taking this medicine. High caffeine intake can result in difficulty sleeping, shaking and an uncomfortable feeling in the chest caused by fluttering heartbeat.

This medicine contains Sodium methyl-, Sodium ethyl- and Sodium propyl-parahydroxybenzoates (E219, E215, E217) which may cause allergic reactions (signs or symptoms may possibly be delayed). The product contains 0.1736mg of sodium per tablet.

Do not take this medicine if you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep. This product is not recommended if you are taking lithium.

Adverse Reaction
When taken in recommended doses, Panadol Extra Advance is unlikely to cause significant undesirable effects and will not upset the stomach. Stop taking this medicine and seek medical advice immediately if you have:

- Allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- A skin rash or peeling, or mouth ulcers.
- Previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction with this product.
- Unexplained bruising or bleeding.

Undesirable effects are rare such as:

- Thrombocytopenia
- Anaphylaxis
- Cutaneous hypersensitivity reactions including skin rashes, angiodema, and Stevens Johnson Syndrome
- Bronchospasm in patients sensitive to aspirin and other NSAIDs
- Hepatic dysfunction
- Nervousness
- Dizziness

When the recommended Acetaminophen-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.


Dosage and Administration
For Oral Administration only.
Adults and children (aged 12 and over): 1-2 caplets (500mg Acetaminophen/65mg caffeine to 1000mg Acetaminophen/130mg caffeine) every 4 to 6 hours as required. Do not take more frequently than every 4 hours. Do not take more than 4000mg Acetaminophen/520mg caffeine (i.e. 8 caplets of Panadol Extra Advance) in 24 hours. Can be taken on an empty stomach.
Children (aged under 12): Take Panadol for Children (in chewable tablets or suspension). Acetaminophen-Caffeine is not recommended for children under the age of 12 years.
Do not exceed the stated dose. Use the smallest dose that you need to treat your symptoms and use the medicine for the shortest period of time necessary.


Overdose
Toxicity is extremely rare following administration of recommended dose. Nevertheless, massive overdose of Acetaminophen may adversely affect the liver of some people and signs or symptoms of overdose may be delayed for up to one week following ingestion. Nevertheless, liver damage is largely reversible if the patient is treated early, thus prompt medical attention is essential in all cases of suspected overdose even if there is no sign or symptom. Administration of N-acetylcysteine or Methionine may be required. Acetaminophen overdose may cause liver failure. Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardiac arrhythmia. CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors and convulsions). It must be noted that for clinically significant symptoms of caffeine overdose to occur with this product, the amount ingested would be associated with serious Acetaminophen-related liver toxicity.

Storage Condition
Store below 30°C
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62-42369

PHARMA CODE REF: IS: 1725





成份最為醫學界採用

主治：更快有效消除頭痛、發燒及各種特強痛症。可於空肚時服用。

成份
每粒含Acetaminophen (Paracetamol) 500mg及Caffeine 65mg。每粒亦含有Pregelatinized Starch, Povidone K-25, Calcium carbonate, Crospovidone, Blend of Sodium Parabens, Purified Water, Alginate Acid, Magnesium Stearate, Opadry White YS-1-7003 and Carnauba Wax。

作用
「必理痛」特效Advance經臨床證實為一快速的止痛退熱藥，並且不會引起胃部不適。「必理痛」特效Advance含有適量的Caffeine，能微妙地刺激中樞神經系統，令疲倦的患者保持清醒；其含量亦能令Acetaminophen發揮更大的止痛效能。

療效
消除特強痛症 (例如：頭痛、偏頭痛、牙痛、咽喉痛、肌肉痛、月經痛)。對治療感冒及過速性病毒感染所引起的發熱及發燒同樣有效。「必理痛」特效Advance更可作牙科手術及拔牙後的有效止痛劑。

注意事項
 1. 本品內含任何成份敏感人士，請勿服用。
 2. 服用本品時，應遵照標籤指示使用本產品。請參閱及依照標籤指示使用本產品。請將此藥及其他藥品放在兒童不易觸及的地方。
 3. 本品含揮發性有機物。若服用超過指定份量之揮發性有機物，可嚴重影響肝臟功能。請參閱及依照標籤指示使用本產品。請將此藥及其他藥品放在兒童不易觸及的地方。
 4. 腎、肝病患者，請於服用前向醫生查詢。如有以下狀況，在服用此藥前請先諮詢醫生：
 5. 體重減輕或營養不良
 6. 有飲酒習慣
 7. 避免與本品一起使用或限制使用揮發性有機物的份量。
 8. 你有嚴重感染，嚴重感染會增加代謝性酸中毒的風險
 9. 代謝性酸中毒的徵狀包括：
 10. 呼吸深、急促及困難
 11. 感到不適 (噁心)；身體不適 (嘔吐)
 12. 食欲不振
 13. 如出現多於一個以上的徵狀，請立即求醫。
 14. 攝入咖啡可能會增加地增加自然產熱機會，故不建議婦女懷孕期間服用此藥物。不建議授乳期間的婦女服用此藥物。母乳內的咖啡可能會含有地刺激服用母乳的初生嬰兒，但至今未有發現顯著咖啡中毒的報導。如正服用Warfarin或抗凝劑，請於服用此藥前向醫生查詢。Warfarin 及其他 Coumarins的抗凝作用可能會因長期服用Acetaminophen而增加出血機會，但仍可以視乎同時服用。
 15. 對於此藥物含有咖啡因，應避免服用過量含咖啡因的飲品，如茶、咖啡，及其他含咖啡因的飲料。吸收高份量的咖啡因可以引起失眠、身體震動及不規律心跳所引起的心悸。
 16. 此藥物含Sodium methyl-, Sodium ethyl- and Sodium propyl-parahydroxybenzoates (E219, E215, E217)，可能會引起過敏反應(其徵狀可能會延遲出現)。此藥物每粒含有0.1736毫克的鈉。
 17. 如正服用處方或非處方治療痛症藥物以治療痛症、發燒、傷風感冒症狀、或用以幫助睡眠，請勿服用此藥。不建議服用藥物的人士服用此藥。

不良反應
 18. 服用量指示使用。「必理痛」特效Advance很少機會引起嚴重的副作用及不會使腸胃不適。如在服用此藥物期間出現以下徵狀，請即停止服用本藥並應儘速延醫處理：
 19. 出現過敏徵狀，如皮膚出疹或瘙癢，喉中響現呼吸困難、喘音、舌腫、咽喉或面部腫脹
 20. 皮膚出疹、脫皮或口腔出現潰瘍
 21. 服用服用阿士匹靈或其他非類固醇類消炎藥出現呼吸困難的徵狀，及在服用本藥期間出現相似徵狀
 22. 出現不明原因的胸痛或流血
 23. 不良反應是罕有的，如：
 24. 血小板減少症 (Thrombocytopenia)
 25. 全身過敏性反應 (Anaphylaxis)
 26. 皮膚敏感如出疹、血管性水腫 (Angioedema)、由Stevens Johnson Syndrome引起的全身性多形性紅斑
 27. 對阿士匹靈及其他非類固醇類消炎藥敏感的病患者或會出現支氣管痙攣 (Bronchospasm)
 28. 肝臟功能障礙
 29. 焦慮
 30. 頭暈
 31. 嚴重副作用：失眠、興奮、頭痛、腸胃不適、心悸。


藥量
 32. 只供口服。
 33. 成人及兒童(十二歲或以上)：每次一至兩粒(500毫克 Acetaminophen/65毫克 caffeine 至 1000毫克 Acetaminophen/130毫克 caffeine)，需要時每隔四至六小時服用一次。請勿於4小時內服用超過一、二十四小時內服用不可超過4000毫克Acetaminophen/520毫克 caffeine，即八粒「必理痛」特效Advance。可於空肚時服用。
 34. 兒童(十二歲以下)：請選用兒童「必理痛」特效Advance。連續服用九粒或藥水。不建議十二歲以下兒童服用Acetaminophen-caffeine。
 35. 不可服用多於指定份量。請在需要時使用最短的時間及最低有效劑量，以減輕症狀。

注意事項
 36. 服用量指示使用。藥物中毒是極罕有的。但服用超過指定份量很多的Acetaminophen，可嚴重影響肝臟功能，其徵狀可能延遲一星期後才出現。不過，在大部份情況，及早治療服用過量，是可能令肝臟回復正常。因此，若有服用過量的情況，即使無任何徵狀，亦應儘速求醫。可能需服用N-acetylcysteine或Methionine作治療。服用超過指定份量的Acetaminophen可能會引起肝衰竭。過量服用咖啡因可能會引起上腹痛、嘔吐、尿頻、心跳過速/心律不正、刺激中樞神經系統(出失眠、心悸不定、興奮、激動、緊張不安、顫抖、抽搐)。如因過量服用此藥而出現過量服用咖啡因的徵狀，會同時出現由Acetaminophen引致嚴重的肝中毒徵狀。

貯存方法
 37. 貯存於30°C以下。
 38. 應將本品置於兒童不易觸及之處。
 39. ©2018 葛蘭素史克集團或其授權人。
 40. 資料更新：2018年3月

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IMPORTANT

GSK LOC is responsible to approve the change documentation, artwork brief and final artwork, ensuring that it is accurate, consistent and complete.

GSK SDC is responsible for site technical requirements and pre-press suitability.

GSK Market is responsible to advise SDC when changes required impact the following:

**Formulation
Tablet embossing
Storage conditions
Shelf Life**

NOTE TO MARKET

Local approvers must ensure that trade mark and copyright statements included in the brief comply with guidance provided by Legal: Global Trade Marks.