

Complaint to TGA: Phoenix Pharmaceuticals Rapid Recovery Hangover Relief

I submit that this is a "critical" complaint because it undermines accepted public health messages about responsible drinking and is likely to lead to harm or injury if the claims are relied upon.

In addition, while one ARTG Public summary is clear that product presentations must not imply or refer to excess consumption of alcohol (which the product promotion does) the other does not.

I also draw the attention of the TGA to a previous CRP upheld complaint for a similar product (2015-03-002, HeadsUp Hangover Relief and more recent complaints to the TGA for a variety of hangover products (AC-JY0FXQ3S/2018).

Publications:

- <https://www.rapid-recovery.com.au/>
- <https://www.chemistwarehouse.com.au/buy/85443/rapid-recovery-hangover-relief-1-dose>
- <http://www.epharmacy.com.au/product.asp?id=85443&pname=Rapid+Recovery+Hangover+Relief+1+Dose>
- <http://www.mychemist.com.au/product.asp?id=85443&pname=Rapid+Recovery+Hangover+Relief+1+Dose>
- <https://daigoudownunder.com.au/collections/hangover-preparations/products/85443>
- <https://www.facebook.com/rapidrecoveryau/>
- Etc.

Date/Edition: 10/09/2018

Products:

- ARTG: 297954 Rapid Recovery
- ARTG: 262916 Rapid Recovery

Sponsor: Phoenix Pharmaceuticals Australia, Postal Address 1089 Killymoon Drive, Hope Island, QLD, 4212

N.B. ARTG Public Summary Indication Inconsistency

ARTG: 297954 Rapid Recovery states (appended)

Permitted Indications

- Helps decrease/reduce/relieve symptoms of occasional hangovers

Indication Requirements

- Product presentation must not imply or refer to excess consumption of alcohol or other toxic substances.

ARTG: 262916 Rapid Recover states (appended):

Specific Indications:

1. Reduces the symptoms of Hangover by 70% and improves well-being by more than 100%.
2. Alleviates Asian Glow.
3. Reverses Oxidative Stress.
4. Reduces Acetaldehyde a toxic metabolism of alcohol which is believed to be a major cause of Hangover symptoms.
5. Assists the Liver to eliminate the toxic effects of alcohol
6. Counters the oxiditative stress produced by alcohol which is damaging to brain cells which may contribute to hangover symptoms.

Complaint to TGA: Phoenix Pharmaceuticals Rapid Recovery Hangover Relief

Advertising claims (see screen shots appended)

- “Rapid recovery”.
- “Clinically proven hangover relief”.
- “Rapid Recovery has been scientifically formulated and clinically proven to treat the symptoms typical of a hangover, such as headaches, nausea, diarrhoea and a lack of concentration”.
- “Made from premium all-natural ingredients and containing powerful anti-oxidants, Rapid Recovery provides the nutrients your body needs after alcohol consumption to break down the toxins alcohol produces”.
- “The liver breaks down alcohol so it can be excreted. However the Liver becomes unable to do this after a few drinks so Rapid Recovery does the job of the liver by removing the toxins (Acetaldehyde) that cause hangovers”.
- “Don’t let a great night out ruin the next day remember to take your rapid recovery”.
- “Rapid Recovery assists the liver to remove acetaldehyde by detoxing both the liver and the brain. You can read more on our website (particularly our scientific study).¹ – *Professor Laurie Howes – Co Inventor of Rapid Recovery & Professor of Pharmacology and Therapeutics.*
- “May Reduce symptoms of hangover by 70%. May Reduce acetaldehyde, a byproduct of alcohol metabolism which is believed to produce hangover symptoms”.

Testimonials²

- “I used Rapid Recovery on a night out, after consuming more than a bottle of wine... I was amazed that the next morning I was able to get out of bed and function normally! No headache and no hangover depression!” - MICHELLE IFFLAND
- "I conducted a trial on the product after about 17 beers with no food other than a dreadful takeaway burger on the way home at 9:45 and can honestly give it a thumbs up! Further trials of 24 beers on a BBQ boat will have to take place soon haha" -MIKE

The study

This involved ten male and nine female subjects who consumed 60-180g of alcohol of their choice, followed by a dose of Rapid Recovery or a placebo. Participants recorded their hangover symptoms the following morning, via a visual scale that depicted how they were feeling.¹

The authors concluded the product could effectively prevent some of the more disabling hangover symptoms, such as nausea, headaches and poor concentration.

But the study has major shortcomings that invalidate the clinically proven claim.³

First, it is poorly designed. There are too few participants, making a false positive error likely. It was held at the sponsor's house and there were no checks of participant blinding, so it's likely the placebo (dextrose) could be distinguished from intervention (Rapid Recovery). The latter was noted to have an “unusual taste”.⁴ This may have influenced the results.

¹ <https://www.rapid-recovery.com.au/study/>

² <https://www.rapid-recovery.com.au/testimonials>

³ <http://www.tgacrp.com.au/decision-highlights>

⁴ <https://www.rapid-recovery.com.au/howitworks>

Complaint to TGA: Phoenix Pharmaceuticals Rapid Recovery Hangover Relief

Second, the authors included the director and major shareholder of the company that produces and markets the product, as well as the honorary medical director who was also a shareholder of the company; a clear conflict of interest.

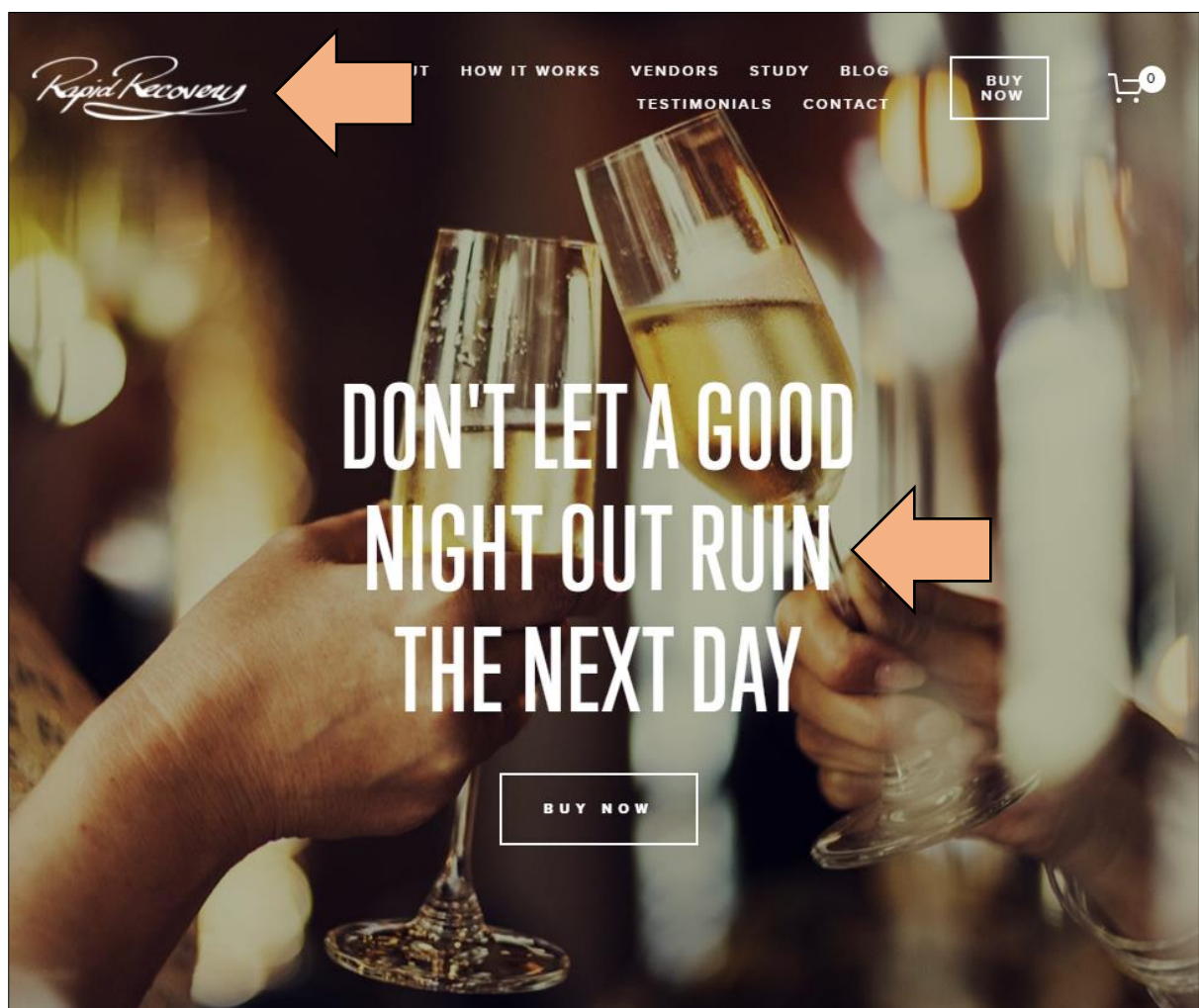
In addition, the overall message of the imagery, text and testimonials is that this product allows people to drink to excess without experiencing a hangover the next day.

In short, in my opinion the promotion of this product undermines public health messages about responsible drinking, is misleading, deceptive and socially irresponsible.

I allege that this product (and its promotion) breaches the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a), 4(2)(c), 4(2)(d), 4(2)(f), 4(2)(h), 4(6)(b)(iv) and 6(3).

I also submit that the permitted indication, "Helps decrease/reduce/relieve symptoms of occasional hangovers" should be revoked (Table 5 - Indications relating to the gastrointestinal system - no 62).⁵

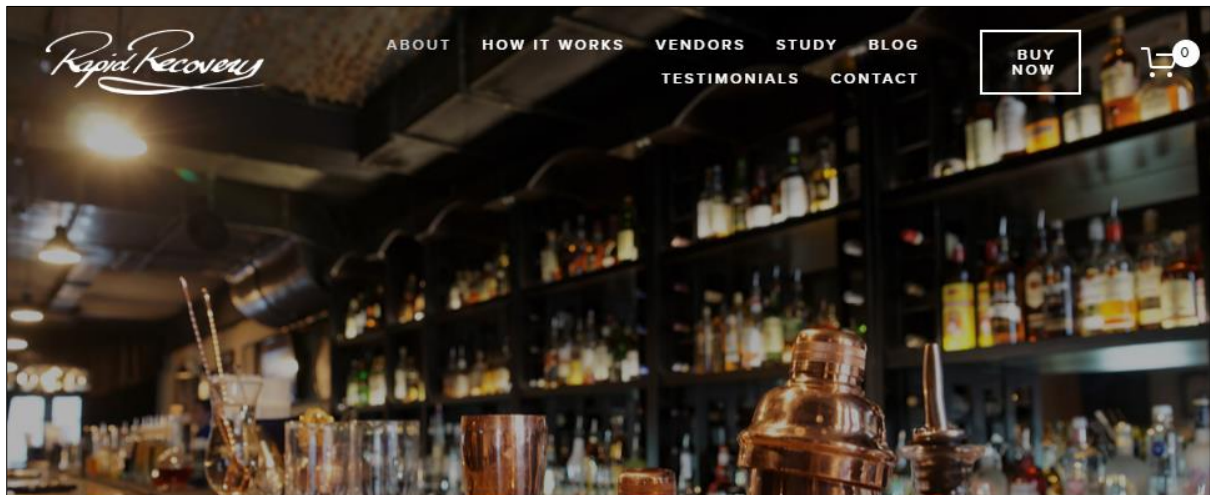
Screen shots (10/09/2018)



<https://www.rapid-recovery.com.au/>

⁵ <https://www.legislation.gov.au/Details/F2018L00215>

Complaint to TGA: Phoenix Pharmaceuticals Rapid Recovery Hangover Relief

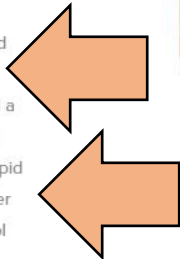


ABOUT

RAPID RECOVERY

In a perfect world we would all know when to stop drinking, in reality, however, this is easier said than done. That's why we created Rapid Recovery.

Rapid Recovery has been scientifically formulated and clinically proven to treat the symptoms typical of a hangover, such as headaches, nausea, diarrhoea and a lack of concentration. Made from premium all-natural ingredients and containing powerful anti-oxidants, Rapid Recovery provides the nutrients your body needs after alcohol consumption to break down the toxins alcohol produces.



<https://www.rapid-recovery.com.au/about/>

Complaint to TGA: Phoenix Pharmaceuticals Rapid Recovery Hangover Relief



<https://www.rapid-recovery.com.au/howitworks/>

DIRECTIONS

Rapid Recovery contains High Potency Vitamins and Amino Acid in a Therapeutic dose. Originally trialled in 200ml of water it does have an unusual taste. Further studies have shown that Rapid Recovery is best mixed thoroughly in around 20ml of a flavoured beverage and washed down with the beverage of your choice.

Take the first dose when you finish drinking and the next dose when you wake up.

HOW DOES RAPID RECOVERY WORK?

RAPID RECOVERY DOES THE JOB OF THE LIVER.

The liver breaks down alcohol so it can be excreted. However the Liver becomes unable to do this after a few drinks so Rapid Recovery does the job of the liver by removing the toxins (Acetaldehyde) that cause hangovers.

REMEMBER

Alcohol lasts in the body for 12-14 hours so **TWO DOSES ARE NECESSARY**. One at the end of drinking and one when you wake up at least 4 hours apart.

Can be made up before you go out so it is ready to take.

DON'T LET A GREAT NIGHT OUT RUIN THE NEXT DAY

HANGOVERS VS DEHYDRATION

The perception that a hangover is merely due to dehydration is a myth that has been propagated by the manufacturers of rehydration products (remember that both alcohol and caffeine will cause a small degree of dehydration, but not enough to cause hangover symptoms).

The best scientific evidence to date, is that the main cause of hangover is the accumulation of a toxic substance called acetaldehyde. Acetaldehyde accumulates because the liver cannot remove it fast enough and it travels to the brain causing the symptoms of hangover.

Rapid Recovery assists the liver to remove acetaldehyde by detoxing both the liver and the brain. You can read more on our website (particularly our scientific study). If you still don't believe me try comparing your hangovers on two occasions, once using rehydration and once using Rapid Recovery.

Another way to see if you are dehydrated is to weigh yourself at the end of an evening drinking then again in the morning. The difference in weight will equal your degree of dehydration. Try drinking any rehydrating drink and see if your hangover is cured. To calculate your level of dehydration you take the difference in your weight from the night before and the morning eg. if you weighed 70kg at night and 69kg in the morning, the difference is 1kg. This is your level of dehydration, 1kg. To rehydrate you need to drink 1 litre of water (it's just as good as any marketed product) but it won't cure your hangover!

– Professor Laurie Howes – Co Inventor of Rapid Recovery & Professor of Pharmacology and Therapeutics.

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Clinical Research and Trials

Research Article ISSN: 2059-0377

A post marketing evaluation of the efficacy of Rapid Recovery in reducing symptoms of hangover

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²School of Allied Health Sciences, Griffith Health, Griffith University, Parkwood, Queensland, Australia
³Professor of Pharmacology and Therapeutics, Griffith and Bond University Medical Schools, Gold Coast, Queensland Australia



<https://www.rapid-recovery.com.au/study/>

Home / Medicines / Hangover Preparations



Rapid Recovery Hangover Relief 1 Dose

D: 85443

★★★★★ 5.0 (3) Write a review

\$8.49

QTY: 1

 **ADD TO CART**

General Information

May Reduce symptoms of hangover by 70%. May Reduce acetaldehyde, a byproduct of alcohol metabolism which is believed to produce hangover symptoms.

<https://www.chemistwarehouse.com.au/buy/85443/rapid-recovery-hangover-relief-1-dose>

Complaint to TGA: Phoenix Pharmaceuticals Rapid Recovery Hangover Relief



<https://www.facebook.com/rapidrecoveryau/>

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10/09/2018



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	262916	Rapid Recovery
ARTG entry for	Medicine Listed	
Sponsor	Phoenix Pharmaceuticals Australia	
Postal Address	1089 Killymoon Drive, Hope Island, QLD, 4212 Australia	
ARTG Start Date	10/11/2015	
Product category	Medicine	
Status	Active	
Approval area	Listed Medicines	

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1. Rapid Recovery

Product Type	Single Medicine Product	Effective date	14/07/2017
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

For the symptomatic relief of hangover.

Specific Indications

1. Reduces the symptoms of Hangover by 70% and improves well-being by more than 100%.
2. Alleviates Asian Glow.
3. Reverses Oxidative Stress.
4. Reduces Acetaldehyde a toxic metabolism of alcohol which is believed to be a major cause of Hangover symptoms.
5. Assists the Liver to eliminate the toxic effects of alcohol.
6. Counters the oxidative stress produced by alcohol which is damaging to brain cells which may contribute to hangover symptoms.

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1. Formulation 1

Dosage Form

Powder, oral

Route of Administration

Oral

Visual Identification

Active Ingredients

Ascorbic acid	300 mg/g
cysteine hydrochloride	310 mg/g
pyridoxine hydrochloride	60 mg/g
Thiamine hydrochloride	30 mg/g

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Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	297954	Rapid Recovery
ARTG entry for	Medicine Listed	
Sponsor	Phoenix Pharmaceuticals Australia	
Postal Address	1089 Killymoon Drive, Hope Island, QLD, 4212 Australia	
ARTG Start Date	22/12/2017	
Product category	Medicine	
Status	Active	
Approval area	Listed Medicines	

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

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Products

1. Rapid Recovery

Product Type	Single Medicine Product	Effective date	13/08/2018 5:23:29 PM
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Permitted Indications

Helps decrease/reduce/relieve symptoms of occasional hangovers

Indication Requirements

Product presentation must not imply or refer to excess consumption of alcohol or other toxic substances.
 Label statement: If symptoms persist, seek the advice of a healthcare professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
 If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

1. Formulation 1

Dosage Form Capsule, hard
Route of Administration Oral

Visual Identification

Active Ingredients

Ascorbic acid	200 mg
cysteine hydrochloride monohydrate	362.12 mg
pyridoxine hydrochloride	10 mg
Thiamine hydrochloride	40 mg

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Public Summary