Instructions and Data for Industry

Multi-Line Rapid Beverage Test Cassette

GHB/BZO/KET

Worlds First Rapid Lateral Flow Assay with Buffer for drink spiking

SureScreen Diagnostics

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Multi-Line Rapid Beverage Test Cassette

GHB/BZO/KET

A rapid beverage test for the qualitative detection of BZO/KET/GHB in beverages.
For beverage safety testing use only

- ✓ Immediate Investigative Response for Police, Sex Crimes Division
- ✓ Identification of Ingested Substances for Non-Responsive Patients
- ✓ Enhancing Emergency Response for First Aid Situations
- ✓ Best Practice for Onsite Licensed Venues

SureScreen Diagnostics
Multi-Line Rapid Beverage Test

A rapid beverage test for the qualitative detection of BZO/KET/GHB in beverages. For beverage safety testing use only.

The Multi-Line Rapid Beverage Test Cassette detects multiple drugs in beverages at the following cutoff concentrations.

Test	Calibrator	Cut-off (µg/mL)
γ-Hydroxybutyric acid(GHB)	γ-Hydroxybutyric acid	500
Benzodiazepines (BZO)	Flunitrazepam	2
Ketamine (KET)	Ketamine	10

This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.

Gas chromatography mass spectrometry (GC/MS) or Liquid Chromatography mass spectrometry (LC/MS) are the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

【SPECIMEN COLLECTION AND PREPARATION】

Beverages Assay

The beverage specimen could be collected in a **clean and dry container**.

Specimen Storage

Beverage specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

【QUALITY CONTROL】

BZO/KET: A procedural control is included in the test. A line appearing in the control region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

【PRINCIPLE】

During testing, a specimen migrates upward by capillary action. A drug, if present in the specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody.

The antibody will then react with the drug-protein conjugate and a visible coloured line will show up in the test region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody.

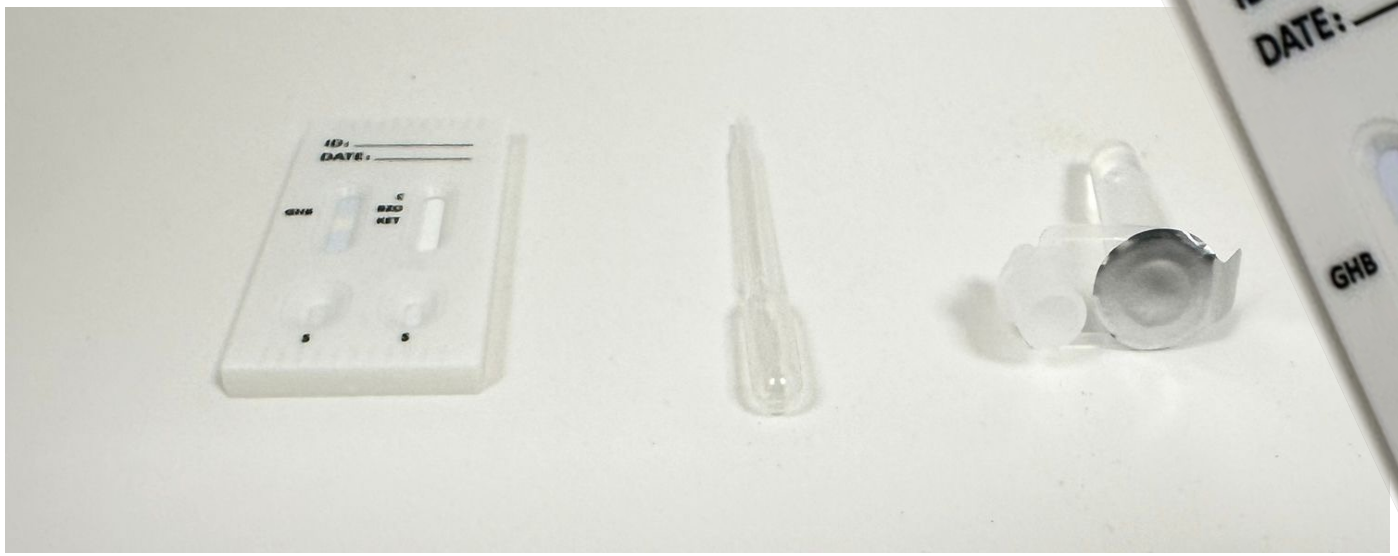
Therefore, the coloured line will not form in the test region. A drug-positive specimen will not generate a coloured line in the specific test region of the strip because of drug competition, while a drug-negative specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a coloured line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

A qualitative assay for GHB requires the dehydrogenase reaction to be pulled to completion by coupling to another reaction. GHB-DH catalyses the reaction of GHB and NAD to produce NADH, and a diaphorase couple tetrazolium dye reaction results in the production of a purple dye complex.

【MATERIALS PROVIDED】

1. Lateral Flow Test cassettes in sealed pouch x20
2. Colour Card (for GHB)
3. Package Insert (IFU)
4. Sample Dilution Buffer Tubes x20
5. Droppers x20



【MATERIALS REQUIRED BUT NOT PROVIDED】

- Specimen collection container
- Timer

【REAGENTS】

Each test line contains anti-drug antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.
The test contains GHB-DH, NAD, Diaphorase, Tetrazolium Dye and Other additives.

【PRECAUTIONS】

- For beverage safety testing use only.
- Do not use the test after the expiration date printed on the package.
- For individually packed test, the test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.
- Users of beverage test kits accept all responsibility for any injury or death that may occur after consuming beverages, whether they have been tested for contaminants or not.
- Please read all the information in this package insert before performing the test.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). However, enzyme-based tests work best when stored at 2-8°C. Therefore, even though the kit is stable up to 30°C, storage at 2-8°C range is advised for enhanced performances.

The test is stable through the expiration date printed. DO NOT FREEZE. Do not use beyond the expiration date.

【DIRECTIONS FOR USE】

Allow the test, beverage specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. **If the reaction pad of the GHB test has a purple colour before applying beverage specimen, do not use the test.**

2. Peel open the aluminium foil on the buffer tube. See illustration 1.

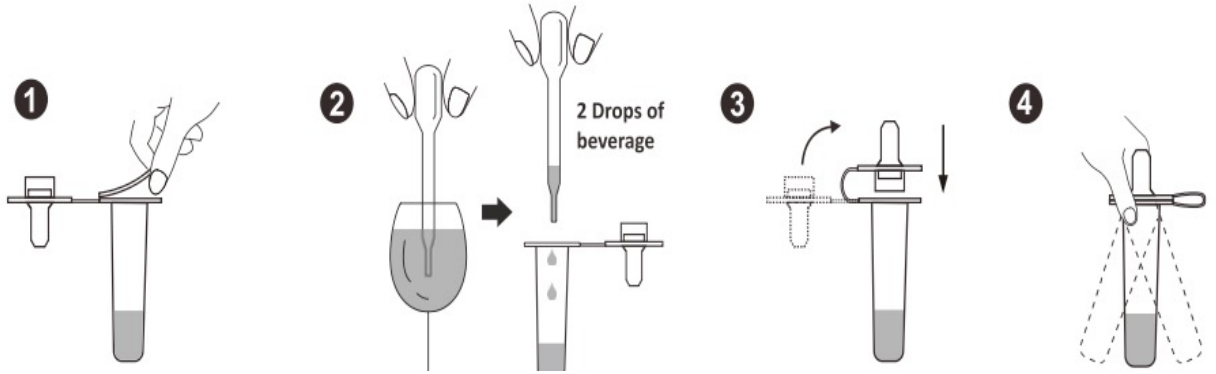
3. Use the dropper to draw a tube of beverage. Transfer 2 drops of beverage (approx. 80μL) to the buffer tube. See illustration 2.

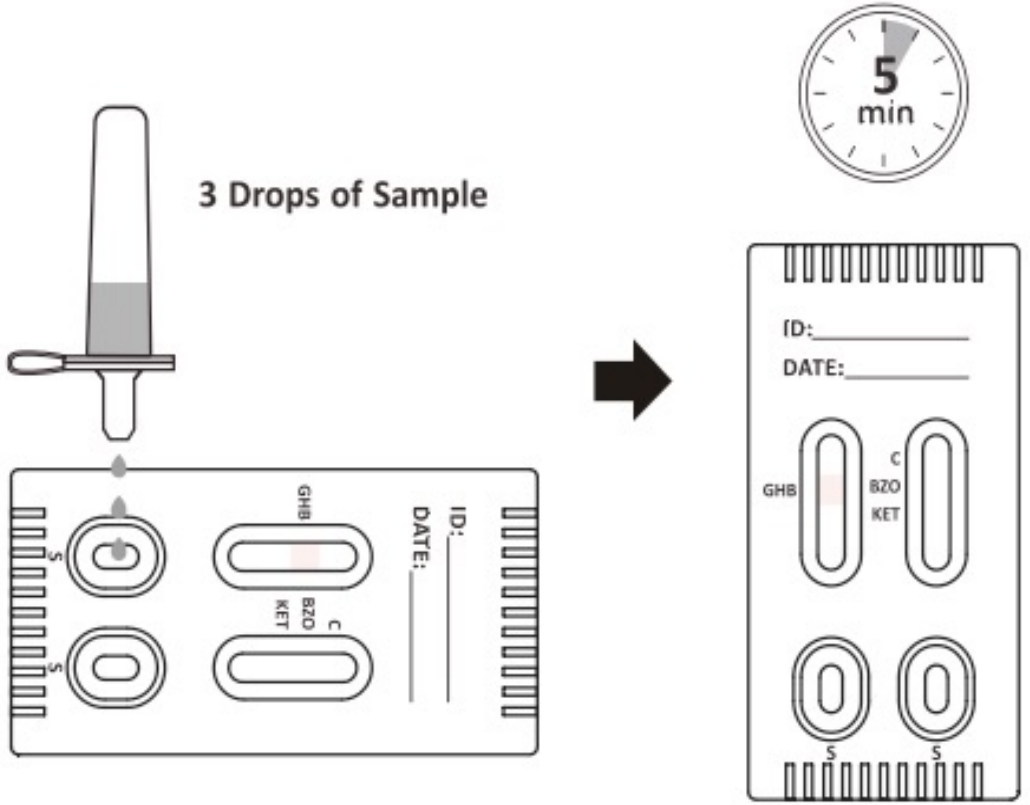
4. Close the lid of buffer tube and shake it from side to side 5-8 times. See illustration 3,4

5. Place the test cassette on a clean and level surface. Hold the tube vertically and **transfer 3 drops of diluted beverage (approx. 120μL)** to the specimen well **(S)** of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S).

6. **Read the GHB pad result at 5 minutes by observing any colour change on the reaction pad**. Do not interpret the result after 10 minutes.

7. **Read the BZO and KET test results at 5 minutes.** Do not interpret the result after 10 minutes.





【INTERPRETATION OF RESULTS】

GHB pad

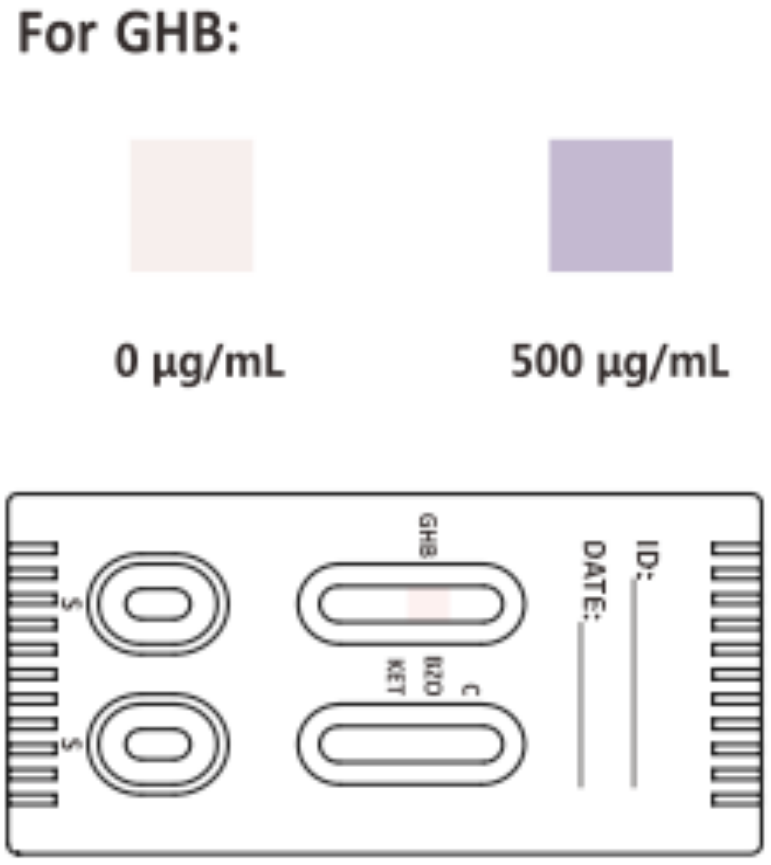
(Please refer to the diagrams on right side of page)

Negative: No colour change appears, or the colour is lighter than positive (500 µg/mL) colour pad, it should be interpreted as a negative result indicating that GHB concentration in the beverage is below 500 µg/mL.

Positive: a dark purple colour greater than or equal to the colour of positive (500 µg/mL) of GHB. It should be interpreted as a positive result indicating that GHB concentration in the beverage exceeds 500 µg/mL.

Invalid: If the colour pad has a purple colour before applying beverage sample, do not use the test.

NOTE: A result where the outer edges of the colour pad produce a slight colour, but the majority of the pad remains colourless the test should be repeated to ensure complete saturation of the pad with specimen.



【INTERPRETATION OF RESULTS】

BZO/KET

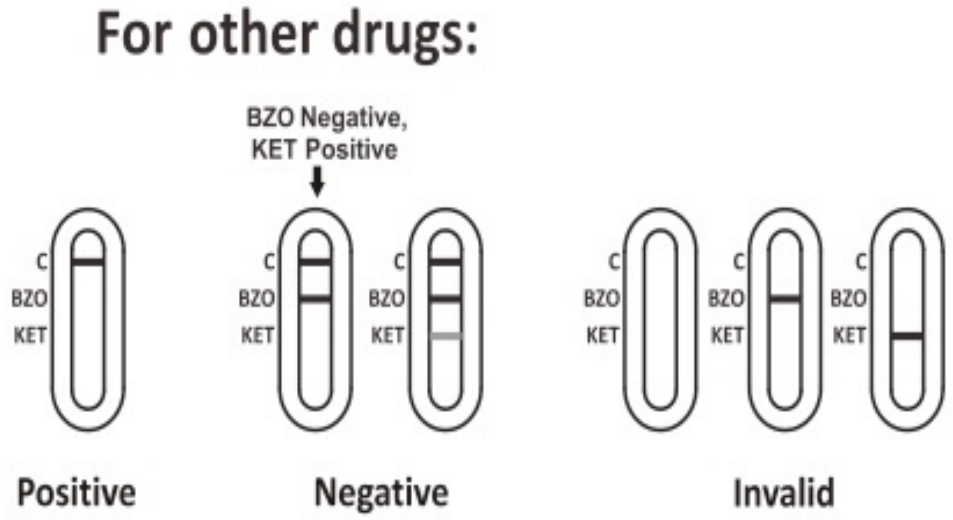
(Please refer to the diagrams on right side of page)

Negative: **Two lines appear. A coloured line appears in the Control region (C) and a coloured line appears in the Test region.** This negative result means that the concentrations in the sample are below the designated cut-off levels for a particular drug tested.

Positive: **A coloured line appears in the Control region (C) and NO line appears in the Test region.** The positive result means that the drug concentration in the sample is greater than the designated cut-off for a specific drug.

Invalid: **No line appears in the Control region (C).** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test panel. If the result is still invalid, contact your manufacturer.

NOTE: The shade of the coloured lines(s) in the Test region may vary. The result should be considered negative whenever there is even a faint line.



【LIMITATION OF PROCEDURE】

1. The Multi-Line Rapid Beverage Test Cassette provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography mass spectrometry (GC/MS) or Liquid Chromatography mass spectrometry (LC/MS) are the preferred confirmatory method [4].

2.Dark condensed juice (such as high concentration Grenadine juice) may affect the background colour of the GHB pad and the performance of BZO/KET product, thus affecting the interpretation of the results. If the concentration of grenadine juice is less than or equal to 10%, it has no effect on the product.

3.It is possible that technical or procedural errors, as well as other interfering substances in the beverages specimen may cause erroneous results.

4.A positive result does not indicate level or intoxication, administration route or concentration in beverage.
5.A negative result may not necessarily indicate drug-free beverage. Negative results can be obtained when drug is present but below the cut-off level of the test.

6.This test does not distinguish between drugs of abuse and certain medications.

【EXPECTED RESULTS】

This negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

【PERFORMANCE CHARACTERISTICS】 Analytical Sensitivity

A drug-free beverage buffer pool was spiked with drugs at the following concentrations. The results are summarized below.

Drug Concentration	n	GHB		BZO		KET	
		-	+	-	+	-	+
0% cutoff	30	30	0	30	0	30	0
-50% cutoff	30	30	0	30	0	30	0
-25% cutoff	30	30	0	30	0	30	0
Cut-off	30	13	17	13	17	16	14
+25% cutoff	30	0	30	0	30	0	30
+50% cutoff	30	0	30	0	30	0	30
3X cutoff	30	0	30	0	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in beverages by the multi-line rapid beverage test cassette at 5 minutes.

Compound	Concentration (μg/mL)	Compound	Concentration (μg/mL)
γ-Hydroxybutyric acid (GHB500)			
γ-Hdroxybutyrate acid	500	Gabapentin	>5,000
4-Aminobutanoic acid	>10,000	2-Hydroxybutanoic acid	>10,000
3-Hydroxybutyric acid	>10,000	Alcohol	>1,000,000
Ascorbic acid	5,000		
Benzodiazepines (BZO2)			
Flunitrazepam	2	Nitrazepam	1.7
Chlordiazepoxide	1.3	Norchlordiazepoxide	1.3
Diazepam	3.4	Nordiazepam	25.1
Temazepam	2.7	Triazolam	16.8
Desalkylflurazepam	8.4	Alprazolam	2.3
Estazolam	4	Bromazepam	2.3
Oxazepam	2	Clobazam	2.3
Lorazepam	67	a-Hydroxyalprazolam	10
Lorazepam glucuronide	6.7	Clonazepam	>100
Sulindac	>100	Bromazolam	2
Etizolam	33.5	Meclonazepam	1.3
Ketamine (KET10)			
Ketamine	10	(±)-Norketamine HCL	400
(R)-Ketamine	100	(S)-Ketamine	2.5

Interference Substance

A study was conducted to determine the interference of the test with compounds in drug-free beverages. The following compounds showed no interference when tested with the multi-line test at the concentration of 100 µg/mL.

Non-Interfering Compounds

The following compounds that may be present in beverages showed no interference when tested with the multi-line rapid beverage test cassette at the corresponding concentration.

Compound	Concentration (µg/mL)	Compound	Concentration (µg/mL)
Sucrose	200,000	Glucose	200,000
Aspartame	1,000	Acesulfame potassium	1,000
Sucralose	1,000	Steviol glycosides	1,000

Non-Interfering Compounds

Acetaminophen	Dextromethorphan	Isoxsuprine	β-Phenylethylamine
Acetone	Diclofenac	Kanamycin	Procaine
Acetophenetidin	Dicyclomine	Ketoprofen	Promethazine
Aspirin	Diflunisal	Labetalol	Quinacrine
Albumin	Digoxin	Lidocaine	Quinidine
Amoxapine	4-Dimethylaminoantipyrine	Lindane	Ranitidine
Amoxicillin	Diphenhydramine	Loperamide	Riboflavin
Ampicillin	5,5-Diphenylhydantoin	Meperidine	Sodium chloride
Ascorbic acid	Disopyramide	Methoxyphenamine	Sulfamethazine
Aspartame	Doxylamine	Metoprolol	Sulindac
Atropine	Dopamine	Nalidixic acid	Temazepam
Benzoic acid	(1R, 2S) - (-)-Ephedrine	(+)-Naproxen	Tetracycline
Bilirubin	Erythromycin	Nimesulide	Tetrahydrozoline
(+/-) Brompheniramine	Ethanol	Norethindrone	Thebaine
Benzocaine	Etodolac	Noscapine	Theophylline
Buspirone	Famprofazone	Niacinamide	Thiamine
Caffeine	Fenoprofen	Norephedrine	Thioridazine
Chloramphenicol	Fluoxetine Hydrochloride	Orphenadrine	Tolbutamide
Chloroquine	Furosemide	Oxalic acid	Trazodone
(+/-)-Chlorpheniramine	Gentisic acid	Oxolinic acid	Triamterene
S- (+)-Chlorpheniramine maleate salt	D (+) Glucose	Oxymetazoline	Trifluoperazine
Chlorpromazine	Guaiacol Glyceryl Ether	Papaverine	Trimethoprim
Chlorprothixene	Hemoglobin	Pemoline	Trimipramine
Cimetidine	Hydralazine	Penicillin-G	Tryptamine
Clomipramine	Hydrochlorothiazide	Perphenazine	Tyramine
Clonidine	Hydroxyzine	Phenelzine	Uric acid
Creatine	Imipramine	Pheniramine	Verapamil
Cyclobenzaprine	Isoproterenol hydrochloride	Phenothiazine	Zomepirac

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[1] Bravo D T, Harris D O, Parsons S M. Reliable, Sensitive, Rapid and Quantitative Enzyme-Based Assay for Gamma-Hydroxybutyric Acid(GHB)[J].Journal of Forensic Sciences, 2004, 49(2):379-387.

[2] Ureda N, Ruan W, French D, et al. Lack of gamma-hydroxybutyrate prevalence among an urban emergency department population[J]. Journal of Analytical Toxicology, 2010, 34(2):110-111.

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γ-Hydroxybutyric acid (GHB)

γ-Hydroxybutyric acid (GHB) is an en-dogenous metabolite in brain and peripheral organs. It has many characteristics of a neurotransmitter and has been studied for potential therapeutic use in the treatment of narcolepsy, drug addiction, and symptoms of withdrawal and to induce anaesthesia.

However, GHB also is widely abused. At higher doses, GHB produces sedation and a trance-like state with loss of memory. Because it has little smell or taste, it can be ingested un-knowingly. This combination of properties has made GHB a “date rape” drug that often is administered to victims in beverages [1,2].

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA).

Because they are safer and more effective, benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Ketamine (KET)

Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug.

Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss of coordination, sense of invulnerability, muscle rigidity, aggressive / violent behavior, slurred or blocked speech, exaggerated sense of strength, and a blank stare.

There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained. The effects of Ketamine generally last 4-6 hours following use [3].

Thank you

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